UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF PENNSYLVANIA

GRAHAM ANDERSON, on Behalf of Himself)) Case No. 2:12-cv-03721-MAM
and All Others Similarly Situated,	
	CLASS ACTION
Plaintiff,	
) AMENDED CLASS ACTION COMPLAINT
v.)	FOR VIOLATION OF FEDERAL
) SECURITIES LAWS
POLYMEDIX, INC., NICHOLAS	
LANDEKIC, EDWARD F. SMITH, and R.	
ERIC MCALLISTER,	
Defendants.	

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I. NATURE OF ACTION

- 1. This is a securities class action brought on behalf of all persons or entities that purchased or otherwise acquired PolyMedix, Inc. ("PolyMedix" or the "Company") common stock on or between March 7, 2011, and May 10, 2012 (the "Class Period") against PolyMedix and certain of its current and former officers and directors ("Defendants"). This complaint seeks relief under the Securities and Exchange Act of 1934 (the "Exchange Act") for losses incurred as a result of Defendants' false and materially misleading statements and omissions during the Class Period concerning the safety and clinical trial progress of PolyMedix's developmental drug compound, PMX-60056.
- 2. PolyMedix is a small clinical stage biotechnology company that develops drugs for the treatment of serious acute care conditions. Throughout the Class Period, the Company had two experimental drugs in clinical development, PMX-60056 and PMX-30063. PMX-60056 is a cardiovascular compound designed to reverse the activity of the common anti-coagulating agents heparin and low molecular weight heparin ("LMWH") in order to prevent unsafe bleeding and restore normal blood-clotting activity. The Company billed PMX-60056 as a safer and more effective replacement for Protamine, which is the only drug currently approved for reversal of heparin. In particular, the Company touted PMX-60056 as presenting a lesser risk of hypotension than Protamine.
- 3. From 2008 to 2010, the Company conducted four Phase I clinical trials to test the ability of PMX-60056 to safely and effectively reverse heparin and LMWH in healthy subjects. According to the Company, PMX-60056 achieved positive safety and efficacy results in each of these studies and in particular, showed only a minimal risk of hypotension that could be avoided with appropriate dosing. Based on the results for these initial studies, the Company initiated a Phase II trial in February 2011 to test the safety and efficacy of PMX-60056 in reversing heparin

¹ The term "Defendants" collectively refers to PolyMedix, Nicholas Landekic ("Landekic"), Edward F. Smith ("Smith"), and R. Eric McAllister ("McAllister").

in patients undergoing percutaneous coronary intervention ("PCI") procedures (the "Phase II Study").

- 4. Throughout the Class Period, Defendants disseminated a series of false and materially misleading statements regarding the safety and clinical trial progress of PMX-60056, including that: (i) the hypotension seen among subjects in the initial Phase I studies for PMX-60056 was transient and not significant; (ii) the risk of hypotension could be completely eliminated by appropriate dosing: (iii) the then ongoing Phase II Study was proceeding as planned and was on track to be completed by the end of 2011; and (iv) the drug was a safer alternative to Protamine because of the purported lack of risk of hypotension.
- 5. In fact, as Defendants revealed on May 10, 2012, PMX-60056 presented such a significant risk of hypotension that the Company was forced to discontinue clinical development of the drug. More specifically, based on facts admitted by Defendants and learned through Lead Plaintiff's investigation, PolyMedix's statements touting the safety and clinical trial progress of the drug were false and materially misleading because the truth was that: (i) in its most recently completed Phase I study, three out of six subjects had significant hypotension with one subject experiencing hypotension to such a significant degree that he required emergency medical treatment for it; (ii) based on the limited scope and results of the initial studies, Defendants' claim that they could completely eliminate hypotension as a side effect of the drug was unfounded; (iii) between fall 2011 and May 2012, Defendants failed to disclose that the Phase II Study for PMX-60056 was encountering significant problems, most notably that it had enrolled only a fraction of the required patients, which was causing significant delays and jeopardizing its ability to complete the study at all and move forward with development; and (iv) between fall 2011 and May 2012, Defendants withheld from the public initial data from the Phase II Study showing a significant risk of hypotension associated with the use of PMX-60056 by patients undergoing PCI procedures.
- 6. On May 10, 2012, PolyMedix issued a press release disclosing for the first time to investors that that the Company had decided to stop enrollment in both PMX-60056 clinical

trials due to observations of reductions in blood pressure. Investors also learned during this time period that PolyMedix was having significant difficulties enrolling patients and was not even close to completing the study as a result. When the true state of PMX-60056's clinical development and adverse side effects became public, PolyMedix's shares sank from a closing pricing of \$0.59 on May 10, 2012, to a closing price of \$0.36 at the end of the day on May 11, 2012. This amounted to a single-day decline of nearly 29%. Defendants' violation of federal securities laws cost unsuspecting investors tens of millions of dollars.

- 7. Defendants deliberately misled the public about the safety of PMX-60056 and the progress of the Phase II Study in order to secure the funding it needed to continue developing its other lead drug compound, PMX-30063. As a development-stage company without any commercially approved products, PolyMedix relies almost exclusively on the debt and equity markets to fund its operations. During the Class Period, Defendants' financial condition grew increasingly worse and they became desperate to raise new capital in order to continue funding their PMX-30063 clinical trial program as it moved into Phase II testing. As a result, Defendants (i) downplayed the risk of hypotension seen in the initial studies for PMX-60056 in order to secure over \$25 million in operating capital; and (ii) concealed the problems with the Phase II Study for PMX-60056 (e.g., incidence of unsafe hypotension and difficulties enrolling patients) until after refinancing the Company's existing debt obligations on highly favorable terms.
- 8. As a result of Defendants' false and materially misleading statements and omissions, Lead Plaintiff and the proposed class acquired PolyMedix securities at artificially inflated prices during the Class Period (the "Proposed Class") and therefore have suffered significant losses and been damaged thereby.

II. JURISDICTION AND VENUE

9. The claims asserted herein arise pursuant to Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §78j(b) and §78t(a), and Rule 10b-5 promulgated thereunder by the U.S. Securities and Exchange Commission ("SEC"), 17 C.F.R. §240.10b-5.

- 10. The Court has subject matter jurisdiction over this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. §78aa, and 28 U.S.C. §1331.
- 11. This is the proper venue for litigation of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. §78aa, and 28 U.S.C. §1391(a), as: (i) one or more of the Defendants reside in this District; (ii) a substantial portion of the acts and transactions giving rise to the legal violations alleged herein, including the public dissemination of false and materially misleading statements concerning PMX-60056, occurred in, or were initiated from, this District; (iii) Defendants have received substantial compensation as a result of doing business in this District; and (iv) Defendants have engaged in numerous activities that had an effect on this District.
- 12. Defendants are individuals or entities with sufficient minimum contacts with this District so as to render the Court's exercise of jurisdiction over each of them permissible under traditional notions of fair play and substantial justice.
- 13. Defendants used, directly or indirectly, the means and instrumentalities of interstate commerce in engaging in the acts, conduct, and wrongs which form the basis of the legal violations asserted herein.

III. PARTIES

Graham Anderson and Franklin Meiyuen Huang, each of whom purchased shares of PolyMedix on two separate occasions during the Class Period. At the time of those purchases, the price of PolyMedix stock was artificially inflated due to Defendants' misrepresentations as alleged herein. The Company's stock price fell dramatically after the truth was revealed, thereby damaging Lead Plaintiff. The certifications attached as Exhibits B and C to the Declaration of Richard A. Maniskas in Support of Movant PolyMedix Group's Motion for Appointment as Lead Plaintiff and Approval of Selection of Counsel filed with the Court on August 31, 2012 (Dkt. No. 8-2), incorporated herein by reference, lists the dates of PolyMedix Group's purchases and the number of shares acquired.

- 15. Defendant PolyMedix is a Delaware clinical-stage biotechnology company that operates through its wholly owned subsidiary, PolyMedix Pharmaceuticals, Inc. ("PPI"). The Company focuses on developing drugs for the treatment of serious acute care conditions using synthetic small molecule compounds referred to as biomimetics. Its principal executive offices are located at 170 North Radnor-Chester Road, Suite 300, Radnor, Pennsylvania.
- 16. Defendant Landekic has been the President, Chief Executive Officer ("CEO"), and a director of PolyMedix since November 2005. Landekic has also been the President, CEO, and a director of PPI since he co-founded it in August 2002. Throughout the Class Period, Landekic made false and materially misleading statements regarding the safety and clinical trial progress of PMX-60056. As an officer and director of PolyMedix and PPI, Landekic was actively involved in the day-to-day operations of the Company and possessed the power and authority to control the contents of its annual reports, press releases, and presentations to securities analysts, money and portfolio managers, and investors (i.e., the market). Landekic was provided with copies of the Company's misleading reports and press releases prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Given his position within the Company, and his access to material, non-public information, Landekic knew that the adverse facts specified herein had not been disclosed to, and were knowingly being concealed from, the public and that the positive representations being made were false and materially misleading. Accordingly, Landekic is liable for his false statements as plead herein.
- 17. Defendant Smith has been PolyMedix's Vice President, Finance and Chief Financial Officer since January 2006. Throughout the Class Period, Smith made false and materially misleading statements regarding the safety and clinical trial progress of PMX-60056. As an officer of PolyMedix, Smith had a substantial role in the day-to-day operations of the Company and possessed the power and authority to control the contents of its annual reports, press releases, and presentations to securities analysts, money and portfolio managers, and investors (i.e., the market). Smith was provided with copies of the Company's misleading

reports and press releases prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Given his position within the Company, and his access to material, non-public information, Smith knew that the adverse facts specified herein had not been disclosed to, and were knowingly being concealed from, the public and that the positive representations being made were false and materially misleading. Accordingly, Smith is liable for his false statements as plead herein.

- Development from January 2011 to August 2011, and Vice President of Clinical Development and Chief Medical Officer ("CMO") from November 2006 to January 2011. During his tenure with PolyMedix, McAllister had a substantial role in conducting, supervising, and monitoring the clinical trials concerning to the Company's two lead drug compounds, PMX-30063 and PMX-60056. Given his positions within the Company, along with his access to material, non-public information, McAllister knew that the adverse facts specified herein had not been disclosed to, and were knowingly being concealed from, the public and that the positive representations being made as to the safety and clinical trial progress of PMX-60056 were false and materially misleading. Accordingly, McAllister is liable for his false statements as plead herein.
- 19. The defendants identified in $\P 16-18$ are collectively referred to herein as the "Individual Defendants."

IV. BACKGROUND

A. Company Overview

20. Founded in 2002, PolyMedix is a clinical-stage biotechnology company that develops synthetic small molecule drug compounds (which are referred to as biomimetics) for the treatment of infectious diseases and cardiovascular disorders. PolyMedix has yet to receive regulatory approval for commercial sale for any of its product candidates. According to its most recent Form 10-K filed with the SEC on March 13, 2012 (the "2012 10-K"), the Company employs only twenty-eight full-time employees, the bulk of whom are focused on research and development.

21. From 2008 to May 2012, PolyMedix had two lead drug compounds in clinical development, PMX-30063 and PMX-60056. As set forth in more detail below, PMX-60056 is a synthetic drug compound designed to reverse anticoagulation following the administration of anti-coagulating agents such as heparin and LMWH. The Company's other drug, PMX-30063, was developed for the treatment of Acute Bacterial Skin and Skin Structure Infections ("ABSSSI") caused by drug resistant strains of staph aureus bacteria.

B. PolyMedix Developed PMX-60056 as a Safer Replacement for Protamine

- 22. PMX-60056 is a drug compound designed to reverse the activity of anti-blood-clotting agents such as heparin and LMWH. During coronary artery bypass grafts ("CABG"), heparin is given to the patient while he or she is on a heart-lung bypass machine to prevent the formation of blood clots. Following the procedure, there is a need to reverse the anticoagulant effects of heparin, which can cause unsafe bleeding, to restore normal blood clotting activity. In addition, heparin and LMWH are frequently used during PCI procedures and often there is a need to reverse them following the procedure as well. LMWH is also designed for long-term use in the prevention of deep vein thrombosis ("DVT"), pulmonary embolisms, and in patients undergoing certain surgeries, such as abdominal surgery, knee replacement, and hip replacement.
- According to its Form 10-K filed with the SEC on March 7, 2011 (the "2011 10-K"), PolyMedix estimates that there are more than two million blood-related procedures annually that may require the reversal of heparin and that up to 20% of the more than twenty million patients receiving LMWH may require a reversing agent. According to PolyMedix, it was developing the drug for use in: (i) reversing heparin following PCI and CABG procedures; and (ii) reversing LMWH for patients who experience unsafe bleeding following the use of it in certain types of surgery or for long-term clot prevention.
- 24. Currently, the only approved drug on the market for reversing heparin is Protamine and it is widely used during cardiology interventional procedures (six to eight million uses per year). Although no drug is currently approved for reversing LMWH, Protamine is occasionally used for this purpose. According to PolyMedix, however, Protamine has significant

safety concerns, chief among them that it causes hypotension. This sentiment was expressed by defendant Smith at the Noble Financial Conference, held on May 16-17, 2011, when he remarked that "one of the significant issues with Protamine, it is highly hypotensive."

25. Throughout the Class Period, PolyMedix repeatedly pointed out this significant side effect of Protamine and stated the need for a putatively safer drug like PMX-60056 to reverse anticoagulants. For example, in a February 9, 2011 press release, defendant Landekic stated "The need for a safer alternative for managing anticoagulation reversal is well understood within the medical community...We are proud to be developing this unique anticoagulant reversing agent to address these important unmet medical needs." Similarly, in its 2011 10-K, the Company stated that it "believe[d] there [was] a significant medical and market need for a safer [heparin reversing agent]."

C. PolyMedix Touts its Testing of PMX-60056 as Inexpensive and Quick

26. A core part of PolyMedix's business plan is to develop drugs that can be quickly tested for efficacy in a clinical setting while simultaneously addressing significant unmet medical needs. Speaking at Cowen & Company's 31st Annual Health Care Conference, held March 7-9, 2011, defendant Landekic summarized this business model as follows:

PolyMedix's mission is ... [to] [d]evelop drugs for life-threatening acute disorders that meet the criteria of addressing large market opportunities, have the possibility of fast and inexpensive development paths, clear clinical endpoints; the questions of the drug work can be easily answered, in early clinical proof of concept.²

According to a Roth Capital Partners analyst report dated May 6, 2011, "[PolyMedix's business strategy] serves a dual purpose of getting much needed therapeutics onto the market as quickly as possible and giving shareholders a strong return for their investment."

27. The Company repeatedly stressed to investors and the medical community alike that one of the major advantages of its PMX-60056 program was that it could be tested

² Defendant Landekic identified PolyMedix's business model in similar terms at the UBS Global Specialty Pharmaceuticals Conference held on May 25, 2011.

inexpensively and quickly because testing required that only a single dose be administered to a small number of patients and the safety and efficacy results could be obtained immediately. Unlike drugs treating chronic conditions, there was no need for dosing regimens to be given over a significant period of time or for long-term monitoring of patients or long-term analysis of data results.

28. On a number of occasions, PolyMedix touted the ease and quickness of conducting PMX-60056 trials. For example, on September 19, 2011, PolyMedix presented at 2011 UBS Global Life Sciences Conference. At this conference, defendant Landekic stated:

[PMX-60056] is a single-dose drug. The development path is very inexpensive and efficient.... It's very easy to tell if the drug works or not....When one has a binary effect like this one, you can see a high degree of significance from a small sample size. This is looking at each individual subject that was in the study. The dirty truth about most drugs is that most drugs barely have any effect. And that's why most clinical trials have hundreds of thousands of patients. You need that size to the tease out statistical significance. When you have an on/off switch, you can see a high degree of significance with a few patients.

Defendant Landekic similarly noted how PMX-60056 had a "very efficient inexpensive development path[]" at Cowen & Company's 32nd Annual Health Care Conference in March of 2012.

D. The Initial Phase I Studies for PMX-60056

1. Description of Phase I Studies

29. Section 312.21 of Title 21 of the Code of Federal Regulations ("Section 312.21") defines Phase I research as the "initial introduction of an investigational new drug into humans" and its research centers primarily on the safety of new drugs in humans. Among other things, this phase explores human metabolic and pharmacological mechanisms, side effects and their relation to specifics doses, and only early evidence of effectiveness. Phase I usually consists of closely monitored studies with typically twenty to eighty normal and patient subjects. Phase I studies allow for the development of "well-controlled, scientifically valid Phase 2 studies." Twenty-seven percent of all investigational drugs that enter Phase I studies are ultimately approved by the United States Food and Drug Administration ("FDA").

2. Phase I Dose-Escalation and Safety Study

- 30. PolyMedix initiated human clinical trials for PMX-60056 in September 2008. The first study it conducted was a Phase I, dose escalation, safety trial consisting of fifteen healthy subjects each of whom received a single low dose of the drug over a ten-minute period ("Study-1"). No heparin or LMWH was administered prior to giving the doses of PMX-60056. The study was completed in March 2009. According to the Company, none of the subjects experienced significant side effects, although a transient, minor decrease in blood pressure was seen in some of the volunteers.
- 31. At the conclusion of the study, the Company stated in a March 11, 2009 press release that it planned to conduct a follow-up study that administered the drug in longer infusion times (of twenty to thirty minutes). The purpose of this study would be to obtain dose-response data, and in particular to explore the relationship between dosing, dosing interval, and hypotensive response. Specifically, the press release announcing the results of this study stated:

This first study has demonstrated that PMX-60056 can be given safely in the absence of heparin if ten-minute infusions include less than 0.4 mg/kg. The data suggest that the limiting side effect of hypotension is related to peak plasma drug level, which means that slower infusions could allow delivery of more drug. To investigate this possibility, PolyMedix plans to study slower infusions, of twenty and potentially thirty minutes, in an extension of this study. These longer infusions are expected to allow higher doses to be given, and will add support for potential clinical studies for the reversal of LMWH, which may require greater total amounts of drug to be administered.

3. Phase IB/2 Proof-of-Concept, Safety, and Efficacy Study for Reversal of Heparin

32. In September 2009, PolyMedix initiated a "double-blind, placebo-controlled, crossover-design pilot, proof-of-concept³, phase 1 [study]" which included six healthy subjects ("Study-2"). In this study, a low dosage of heparin was given to each volunteer followed by a

³ In the drug development context, a proof of concept trial is "carried out to determine if there is early evidence of clinical efficacy using a small, targeted number of subjects, to warrant taking a drug further in development." Ann Leung, et al., *Innovative Proof-of-Concept Designs for Phase I/II and IIIb Studies*, Scian News, Vol. 9, No. 1, Fall 2006. For PMX-60056, the desired clinical efficacy result was the full reversal of heparin and/or LMWH.

ten minute IV infusion of either a single dose of the drug or a placebo. Then, two days later, each volunteer was tested again and received the opposite of what they had received the first time.

33. The Company completed the study and reported results for it in October 2009. According to the 2011 10-K, the study met all efficacy and safety endpoints. The Company described the safety results as follows:

PMX-60056 was well tolerated in this study, with no serious or reportable adverse events occurring. Subjects in the study experienced minimal side effects, which consisted of.... brief reductions in blood pressure, which were transient and not clinically significant...

4. Phase IB/2 Dose-Ranging, Safety, and Efficacy Study for Reversal of Surgical Levels of Heparin

34. On April 10, 2010, PolyMedix began an open label, dose titration, heparin reversal study ("Study-3").⁴ According to PolyMedix's poster presentation at the American Society of Hematology ("ASH") Annual Meeting held on December 6, 2010 (the "2010 ASH Meeting") the purpose of the study was to "examine dose-response⁵, efficacy, and safety" at

One of the most important principles of pharmacology, and of much of research in general, is a concept called "dose-response." Just as the term implies, this notion refers to the relationship between some effect – let's say, lowering of blood pressure – and the amount of a drug. Scientists care a lot about dose-response data because these mathematical relationships signify that a medicine is working according to a specific interaction between different molecules in the body.

... Scientists most often plot data from dose-response experiments on a graph. A typical "dose-response curve" demonstrates the effects of what happens (the

⁴ In March 2010, PolyMedix also initiated a phase 1B/2 safety and efficacy study for reversal of LMWH ("Study-4"). This study enrolled six healthy volunteers who each received a specific dose of LWMH followed by a ten-minute intravenous infusion of either PMX-60056 or a placebo. According to the 2011 10-K, Study-4, which was completed in June of 2010, "met the efficacy and safety endpoints" with "no serious or reportable adverse events" occurring. As this study supported the Company's efforts to develop PMX-60056 for use in the reversal of LMWH, a separate indication of use requiring a separate clinical trial process than the use of PMX-60056 following PCI and/or CABG procedures.

⁵ In the drug development context, the term "dose response" refers to the clinical effect(s) (whether desirable or undesirable) caused by the introduction of a drug at varying levels and over varying periods of time. According to the National Institute of General Medical Sciences' booklet entitled Medicines by Design:

highest levels (i.e., surgical levels) of heparin. The primary safety endpoint was to examine whether using the higher doses of PMX-60056 that were necessary to counter the higher levels of heparin caused significant changes to blood pressure. The study tested twelve healthy volunteers. As part of the study, six of the subjects were given surgical doses of heparin followed by initial ten minute infusions of .7 mg/kg of PMX-60056. Small, discrete amounts of additional infusions were given until the heparin was fully reversed.

- 35. In August 2010, PolyMedix completed and reported the results of Study-3. According to the March 7, 2011 10-K, the study met "the safety and efficacy endpoints in both the reversal of surgical levels of [heparin] and in subsequent re-anti coagulation with [heparin] and re-reversal with PMX-60056." Specifically, PolyMedix described the safety and efficacy results of Study-3 as follows:
- (a) The study showed that PMX-60056 could "reverse the highest dose [of heparin (i.e. surgical doses)] ever given." *See* defendant Smith's presentation at the Noble Financial Capital Markets Seventh Annual Equity Conference dated May 7, 2011.
- (b) No significant hypotension (or any other side effect) was seen in Study-3. More specifically, the 2011 10-K stated, in relevant part, that:

PMX-60056 was well tolerated in this study, with no serious or reportable adverse events occurring. Subjects in the study experienced minimal side effects, which consisted of transient reductions in blood pressure, which were not clinically significant and were seen only at the end of some reversals when ACT was already nearing baseline after the last dose of PMX-60056.

(c) "No hypotension occurred until heparin had been exhausted" and only excess PMX-60056 remained. *See* defendant McAllister's data presentation entitled *PMX-60056*

vertical Y-axis) when more and more drug is added to the experiment (the horizontal X-axis).

U.S. Dept. of Health & Human Servs., Nat'l Inst. of Gen. Med. Sci., Medicine by Design (2006).

In other words, the creation of a dose-response relationship through the plotting of data points on a dose-response curve is crucial to determining whether a given drug is actually safe and/or efficacious.

Reverses Heparin – Predictability and Safely, given at the CREF 31st Annual Cardiothoracic Surgery Symposium held on March 11, 2011.

- (d) Through the study, "a dose-response curve ha[d] been worked out." See id.
- (e) Based on its reported findings that a linear dose-response relationship had been established and that only excess of the drug caused hypotension, the Company declared that "dosing in Phase II should be highly predictive and easy to calculate." *See* defendant Smith's presentation at Noble Financial Capital Markets' Seventh Annual Equity Conference held on May 7, 2011.

E. Citing the Positive Results From the Initial Phase I Studies, the Company Billed PMX-60056 as a Safe Alternative to Protamine

- 36. Throughout the Class Period, PolyMedix repeatedly touted the positive safety and efficacy results from the initial studies and promoted the drug as a safer and more effective version of Protamine. In particular, Defendants emphasized that while Protamine presented a significant risk of hypotension, the initial studies showed that PMX-60056, in comparison, presented only a minimal risk of hypotension that could be entirely avoided with appropriate dosing. For example, at the 2010 ASH Meeting on December 6, 2010, defendant McAllister stated: "Efficacy and safety [for PMX-60056] have been demonstrated in 4 phase 1 trials.... [P]rotamine reportedly has hypotensive effects on first exposure, while PMX-60056 has none unless there is drug in excess of the amount needed for heparin reversal."
- 37. Similarly, on March 7, 2011, at the Cowen & Company 31st Annual Health Care Conference, defendant Landekic summarized the safety results of the initial studies as follows: "The conclusions from these studies were that there were no clinically meaningful or statistically significant changes seen in blood pressure, which we believe is much better tolerated than would be with the Protamine."
- 38. Finally, on May 17, 2011, at the Noble Financial Capital Markets Seventh Annual Equity Conference, Smith noted in his presentation that Protamine "can cause serious

hypotension" whereas hypotensive effects for PMX-60056 are "believed only with excess drug" and are expected to be "more manageable than [in] protamine."

- 39. More specifically, both before and during the Class Period, the Company made numerous statements claiming that it could identify the exact dosages of PMX-60056 needed to safely and effectively heparin. For example, at the 2010 ASH Meeting held on December 6, 2010, defendant McAllister delivered a presentation entitled *Reversal of Heparin by Novel Synthetic Antagonist PMX-60056 Exhibits a Linear Dose-Response Relationship*, in which he stated: "These data suggest that measurements routinely available during cardiac surgery are sufficient for predicting a single reversing dose of PMX-60056 that will safely and effectively neutralize [heparin]-induced anticoagulation." In the Summary portion of the presentation, defendant McAllister went on to state that "PMX-60056 predictably, safely, and completely reverses the anticoagulation effects of high doses of [heparin] in man" and, as a result, "[c]omplete reversal can be obtained without adverse effect by computing the appropriate dose using a similar linear relationship." In conclusion, McAllister succinctly stated that any risk of hypotension associated with the use of PMX-60056 "can be completely avoided."
- 40. PolyMedix's assurances that it could eliminate the risk of hypotension associated with the use of PMX-60056 by appropriate dosing was based on its supposed findings from the initial studies that: (i) only excess of the drug causes hypotension; and (ii) a linear dose-response relationship had been conclusively established meaning it could figure out the exact dose required to fully reverse a given amount of heparin.
- 41. Before and throughout the Class Period, Defendants stated on multiple occasions that the only circumstance that can cause hypotension is if excess of the drug is given to the subject.
- (a) For example, on April 28, 2011, at the American Heart Association's ("AHA") Arteriosclerosis, Thrombosis, and Vascular Biology (ATVB) 2011 Meeting, defendant McAllister gave a presentation in which he stated that "PMX-60056 has [no hypotensive effects] unless there is drug in excess of the amount needed for heparin reversal."

- (b) On May 3, 2011, PolyMedix issued a press release in which defendant McAllister stated that "only an excess of unbound PMX-60056 appears to contribute to any transient hypotension." This sentiment was reiterated on May 17, 2011, by defendant Smith during a presentation at the Noble Financial Capital Markets Seventh Annual Equity Conference in which he stated that hypotensive effects for PMX-60056 are "believed only with excess drug."
- 42. In addition, Defendants claimed to have found a precise dose-response relationship that, when combined with their finding that only excess of the drug causes hypotension, would allow them to identify precise dosages of PMX-60056 that would eliminate any and all risk of drug-related hypotension. Indeed, on September 12, 2011, PolyMedix presented at the Rodman & Renshaw Global Investment Conference. During the presentation, defendant Landekic stated:

And most importantly what's the dose response correlation? What's the relationship between how much drug you have to give for how much heparin you want to reverse? You can see here it's a very, very linear relationship, it's very precise and highly predictable relationship of how much drug you have to give. This should make this drug very easy, very straightforward, very simple to use.

Similarly, on May 25, 2011, PolyMedix presented at the 2011 UBS Global Specialty Pharmaceuticals Conference. At this conference, defendant Landekic stated:

Most importantly, this study established the dose-response correlation, and the relationship is very, very tight. How much of our drug you need to give is extremely tied into relationship of how much heparin you want to reverse. The correlation coefficient r^2, is greater than 0.96. So very, very predictable.... This makes the drug very straightforward to give, very easy to dose...

F. The Market's Positive Reaction to the Company's Statements Touting the Results of the Initial Phase I Studies

43. The financial market responded favorably to the Company's reporting of positive results for the initial studies of PMX-60056, viewing it as significantly boosting the Company's prospects for successful development of PMX-60056. In particular, analysts responded to the Company's claimed positive results for the initial studies by reiterating their "Buy" rating and raising their price targets to as high as \$5. In setting their ratings and price targets, these equity analysts took at face value, and relied upon, Defendants' assertions that the hypotension seen in

the initial studies was minor and that it could easily be eliminated as a side effect with appropriate dosing. For example, a Cowen & Company report dated April 25, 2011, parroted Defendant's statements that "[n]o clinically significant differences in hypotension between PMX-60056 and placebo were observed in the [Study-3]" and the "transient" drop in blood pressure which was seen occurred "only when there [was] excess 'free' or 'unmatched' PMX-60056, i.e. PMX-60056 that is not bound to heparin." Thus, relying upon the Company's reported results for the initial studies, the analyst concluded that hypotension was not a significant issue with PMX-60056:

Is PMX-60056 safe? Based on what we've seen so far, and barring any unpleasant surprises in the Phase II setting, the main adverse event that investors would be concerned about is hypotension. Even though we view any drug-related changes in blood pressure as worthy of serious attention, we do not believe that the hypotension observed with PMX-60056 in its trials thus far is one that would cause significant issues for the compound's development or potential commercial success. The reason is that the drug that PMX-60056 would be competing with, protamine, is also known to cause hypotension, of similar and even higher magnitude, given it is also a positively charged molecule. We thus believe that if PMX-60056 continues to demonstrate efficacy and safety similar to what has been observed in its trials thus far, hypotension of the transient nature and relatively mild in magnitude should not become a major hurdle in the compound's further development.

44. Dr. Yigai' D. Nochomóvitz of Rodman & Renshaw similarly noted that "PolyMedix has also demonstrated the potential for PMX-60056 to re-reverse subjects following re-heparinization, with no signs of hypotension" in an October 17, 2011 research report.

G. The Phase II Study for PMX-60056

1. Description of Phase II Studies

45. Phase II involves a thorough investigation of the effectiveness in the patient population. This phase includes studies designed to explore general effectiveness for the specified condition and common short-term side effects. According to Section 312.21, Phase II consists of "well controlled, closely monitored" studies involving several hundred patients. Twenty-seven percent of all investigational drugs that enter Phase II studies are ultimately approved by the FDA.

2. FDA Guidance

46. After completing four initial Phase I trials, PolyMedix sought to move into Phase II studies by testing the drug on patients undergoing CABG procedures. On October 21, 2010, PolyMedix reported that it had recently engaged in an End of Phase I meeting with the FDA and that during this meeting, FDA had advised PolyMedix to first conduct a Phase II study on PCI patients before testing it on CABG patients. Based on this advice, PolyMedix decided to launch a Phase II clinical trial in PCI patients in early 2011.

3. Design and Purpose of the Phase II Study

47. On February 9, 2011, PolyMedix issued a press release announcing that it had commenced a Phase II clinical trial to test the safety and efficacy of PMX-60056 in reversing heparin in patients undergoing PCI procedures. The press release described the design and purpose of the Phase II Study as follows:

This multi-center, open-label Phase 2 clinical study is intended to enroll up to 40 patients undergoing PCI in the United States. All patients will receive PMX-60056 by intravenous infusion, in a dose calculated to reduce the post-procedure ACT (activated clotting time) to less than 30 seconds above the baseline level. The primary endpoint of the study is to evaluate the safety and efficacy of PMX-60056 in reversing heparin in a surgical setting. Data collected from this study are intended to support further development of PMX-60056 in larger and more diverse patient populations. The study is expected to be completed by the end of this year.

4. The Results of the Phase II Study Were Key to the Company's Success

- 48. Throughout the Class Period, both the Company and financial analysts alike repeatedly stated that the results of the Phase II Study for PMX-60056 were a crucial milestone for the Company and a key value driver for the Company moving forward.
- 49. For example, on September 12, 2011, PolyMedix presented at the Rodman & Renshaw Global Investment Conference. During the presentation, defendant Landekic noted that the Company's upcoming announcements of the results for the Phase II Study and Phase Ib/2 study⁶ for PMX-60056 would be significant events for the Company, stating:

⁶ This study was designed to support the Company's development of PMX-60056 for use in reversing LMWH in long-term clot prevention and following certain other types of procedures.

So, to wrap up over the next two months we have multiple clinical events we can look forward to, two clinical studies with 60056, completing the Phase 2 PCI study and completing another efficacy study reversal of [Lominox].... So multiple clinical events in the next 6 months, so a lot of clinical milestones coming up.

- 50. On November 16, 2011, at the Lazard Capital Markets 8th Annual Healthcare Conference, defendant Landekic reiterated that that one of the upcoming "clinical milestones" was the reporting of results from the Phase II Study for PMX-60056, which were "expected by the end of the year."
- 51. Analysts were also were anxiously awaiting the results of the Phase II Study, as they viewed this clinical event as a key indicator of the Company's ability to successfully develop PMX-60056, particularly because a successful Phase II trial would show that they were far enough along in development to attract a funding partner for the remaining clinical development and commercialization of the drug. For example, a Cowen & Company analyst report dated April 25, 2011, stated: "We expect that upon successful completion of the Phase II program, PolyMedix would initiate a Phase III program with PMX-60056 and have assumed that the Phase III program would be conducted in collaboration with a pharma partner... that would fund at least a portion of the clinical development program."
- 52. A Rodman & Renshaw analyst report dated August 1, 2011, stated that if "th[e] Phase II [study for PMX-60056] is positive, it should be a significant value-generating event for PolyMedix."
- 53. A Rodman & Renshaw analyst report dated October 17, 2011, stated that "[d]ata for ongoing Phase II Studies [for PMX-60056] is Key Value Driver in 4Q11."
- 54. In addition, based on the Company's above public statements, throughout 2011, financial analysts repeatedly stated that they anticipated that PolyMedix would report its results

Specifically, in the September 27, 2011 press release, the Company stated that the study was designed to "evaluate the safety and efficacy of PMX-60056 in reversing the anticoagulant activity of enoxaparin (Lovenox), a LMWH."

for the Phase II Study by the end of 2011. For example, a Rodman & Renshaw analyst report dated August 1, 2011, listed the "Completion Date" and "Results Reported" Data as YE 2011.

55. After PolyMedix reported on September 12, 2011, that, in keeping with its original timeline, it expected to release results for the Phase II Study by the end of the year, a Cowen & Company analyst report dated September 12, 2011, stated:

This morning PolyMedix provided an update on timelines on its two Phase II programs, PMX-60056, its heparin and LMWH... reversing agent and PMX-30063.... We don't expect any significant impact on PYMX shares based on these timeline updates; we continue to expect the data from the following ongoing trials to be the next important milestones for PYMX, most of which are expected in the next few months... data from the 40-patient Phase II trial of PMX-60056 in PCI... expected YE2011... data from the Phase 1b/II dose ranging study of PMX-60056 in the reversal of Lovenox, expected YE2011....

56. A Rodman & Renshaw analyst report dated October 17, 2011, stated that "[t]op-line data for both [the Phase II and Phase IB/2] studies [for PMX-60056] [were] anticipated in late 4Q11." A Rodman & Renshaw analyst report dated October 24, 2011, stated that PolyMedix was expected to "report top-line data" from both its Phase II study and Phase Ib/2 Study in 4Q11the fourth quarter of 2011.

5. Updates on the Phase II Study

- 57. Throughout the Class Period, Defendants led investors to believe that the study was proceeding as planned and stated that they were on schedule to complete the study by the end of 2011. At no time did they give any indication that they were encountering any problems or delays with the trial. For example, on March 7, 2011, at the Cowen & Company 31st Annual Health Care Conference, defendants Landekic provided the following update on the status of the Phase II Study: "Last month we started a phase two clinical trial in PCI, Percutaneous coronary intervention. This is a study with up to 40 patients and we expect to have the results late this year."
- 58. Two months later, on May 17, 2011, defendant Smith presented at the Noble Financial Capital Markets Seventh Annual Equity Conference. During the presentation, defendant Smith offered the same timeline for completion of the Phase II study, stating:

In terms of next steps and what's going on in this program, in February of this year we commenced a Phase II study. That's a Phase II study in up to 40 patients undergoing percutaneous coronary intervention. We expect to have results from that study before the end of this year.... At this point we have two first in-class drugs....both of which are in Phase II. Both have very encouraging safety and efficacy profiles from what we've seen in the data so far and both of which we expect the data from Phase II to read-out later this year.

- 59. On May 25, 2011, PolyMedix presented at the 2011 UBS Global Specialty Pharmaceuticals Conference. During the presentation, defendant Landekic stated: "So based on all these results, [indiscernible] the Phase II clinical studies in PCI reversal of heparin after a life of percutaneous coronary intervention. The study has 40 patients and we expect the study to be completed by the end of this year."
- 60. On September 12, 2011, PolyMedix issued a press release announcing updates on the lead clinical programs. In regards to clinical development for PMX-60056, the press release stated, in part:

Earlier this year PolyMedix initiated a Phase 2 clinical trial to evaluate the safety and efficacy of PMX-60056 in reversing heparin in patients undergoing Percutaneous Coronary Intervention (PCI) procedures. This multi-center trial is designed to enroll up to 40 patients in the United States. All patients in the trial will receive PMX-60056 by intravenous infusion. Enrollment is on-going and the trial is expected to be completed by the end of this year.

61. On September 19, 2011, PolyMedix presented at the 2011 UBS Global Life Sciences Conference. At this conference, defendant Landekic stated:

Based on all these studies, earlier this year, we started a Phase II study in PCI, essentially, angioplasty and cardiac catheterization. An open label study with 40 patients testing safety in a cardiac-compromised patient population and, of course, efficacy. The ability of a single dose of 60056 to reverse heparin, normalized clotting time and shorten time to sheath removal. We expect to have the results of the study by the end of this year.

62. On November 16, 2011, PolyMedix presented at the Lazard Capital Markets 8th Annual Healthcare Conference. At this conference, defendant Landekic provided an update on the status of the Phase II Studies:

We have 2 efficacy studies currently underway. We have a Phase II study underway in TCI, reversal of heparin, following cardiac catheterizations and stent placements, and the second efficacy study underway for reversal of enoxaparin, the low molecular weight heparin Lovenox. And in the coming weeks and coming months, we expect to have results including by the end of this year in these ongoing studies as well.

of 2011 Defendants did not, in fact, report any results, either interim or final, by the end of the year. Between December 2011 and May 2012, Defendants offered only sporadic updates with minimal information regarding the status of their Phase II and Phase Ib/2 studies for PMX-60056. In these cursory updates, they never disclosed that they were having any problems with the studies and continued to give investors the impression that the studies were proceeding smoothly and would be completed in the next few months.

6. PolyMedix Discontinues the Clinical Development of PMX-60056

64. On May 10, 2012, in conjunction with the filing of its 10-Q for the first quarter of 2012, PolyMedix announced to investors that it had "stopped enrollment in two clinical trials for PMX-60056: a Phase II clinical trial for reversing the anticoagulant activity of unfractionated heparin (UFH) in patients undergoing percutaneous coronary intervention procedures, and a Phase Ib/2 clinical trial for reversing the anticoagulant activity of the low molecular weight heparin enoxaparin in healthy volunteers." Its press release also disclosed for the first time that PolyMedix would "instead focus its development efforts and resources on PMX-30063." Providing more detail, the press release stated, in part:

PolyMedix decided to stop enrollment in both clinical trials [for PMX-60056] due to observations of reductions in blood pressure. PolyMedix believes these side effects could be addressed with PMX-60056 being delivered in a larger volume over a longer infusion time. Furthermore, given the Company's limited resources and current capital market conditions, PolyMedix has made the strategic decision to not incur additional expenses relating to the PMX-60056 program and instead focus its development efforts and resources on PMX-30063.

65. In mid-May 2012, investors also learned that PolyMedix had encountered significant problems with the Phase II Study, and in particular that it had enrolled only a fraction of the patients needed to complete the study. According to information at the website ClinicalTrials.gov which was updated in mid-May 2012 by PolyMedix, as of the date that the Phase II Study was discontinued, PolyMedix had enrolled only seventeen patients at the three clinical sites.

H. PolyMedix's Deteriorating Financial Condition and Capital Raising Efforts

1. Overview

- 66. PolyMedix has incurred operating losses every year since its inception in 2002, failing to generate a profit or record any sales revenue at all during its history. In the 2011 10-K, the Company indicates that this trend is not likely to stop anytime soon, stating "[PolyMedix] expect[s] to continue to incur significant and increasing operating losses ... for the foreseeable future." This sentiment is reiterated in the 2012 10-K which states "[PolyMedix] will not be able to generate revenue from product sales or royalties unless and until we receive regulatory approval and begin commercialization of our product candidates.... We are not certain of when, if ever, that will occur."
- 67. Given its lack of any sales or licensing revenue stream, the Company has financed its operations primarily with the proceeds from its equity offerings and by accessing the debt markets, supplemented by a few government grants and research contracts. Unfortunately, it became increasingly more difficult to obtain financing during the Class Period. As noted in the 2012 10-K, "[f]unding, especially on terms acceptable to [PolyMedix], may not be available to meet [its] future capital needs because of the state of the credit and capital markets." The 2012 10-K continues, stating:

[T]he cost of raising money in the debt and equity capital markets has increased substantially while the availability of funds from those markets has diminished significantly. Also, as a result of concern about the stability of financial markets generally and the solvency of counterparties specifically, the cost of obtaining money from the credit markets has increased as many lenders and institutional investors have increased interest rates, enacted tighter lending standards and reduced and, in some cases, ceased to provide funding to borrowers. Low valuations and decreased appetite for equity investments, among other factors, may make the equity markets difficult to access on acceptable terms or unavailable altogether.

This lack of readily available funding severely jeopardized PolyMedix's ability to further develop its core drug compounds, PMX-60056 and PMX-30063. Specifically, as noted in the 2012 10-K: "If funding is not available when needed, or is available only on unfavorable terms, meeting our capital needs or otherwise taking advantage of business opportunities may

become challenging, which could have a material adverse effect on [PolyMedix's] business plans."

- 68. Defendants were acutely aware of the need to keep the Company's stock price inflated in order to secure financing on favorable terms. The 2012 10-K specifically notes how a "decline in the price of [PolyMedix's] common stock could affect [its] ability to raise further working capital." It goes on to state that:
 - a decline in the price of [PolyMedix's] common stock could be especially detrimental to our liquidity and our operations. Such reductions may force us to reallocate funds from other planned uses and may have a significant negative effect on our business plans and operations, including our ability to develop our product candidates and continue our current operations. If our stock price declines, it may be more difficult to raise additional capital. If we are unable to raise sufficient capital in the future, and we are unable to generate funds from operations sufficient to meet our obligations, we will not be able to have the resources to continue our normal operations.
- 69. During the Class Period, the Company engaged in substantial equity and debt offerings, which the Company depended on to fund its PMX-60056 and PMX-30063 Phase II clinical trials. Most notably, PolyMedix engaged in a \$20 million equity offering in April 2011 and was a party to a number of credit facilities totaling over \$25 million, the details of which are discussed herein. Although these capital infusions were much needed to continue funding in its most recent Form 10-Q filed with the SEC on November 9, 2012 (the "November 2012 10-Q"), PolyMedix states that its remaining "cash and investment balances [of \$7,1333,000] *will not be sufficient* to fund [its] operations" through 2013.

2. The Hercules Technology II, L.P. Credit Facility

- 70. On March 31, 2010, PolyMedix entered into a Loan and Security Agreement with Hercules Technology II, L.P. ("Hercules") for \$14 million (the "Hercules Credit Facility"). At signing, PolyMedix obtained an initial advance of \$10 million for use in the "clinical development of PMX-30063 and PMX-60056."
- 71. The Hercules Credit Facility had a forty-two month term, bore a variable interest rate of 12.35-14%, and required interest-only payments for the first nine months. It also contained a provision which required PolyMedix to pay a prepayment penalty equal to: (i) 3% of

the principal being prepaid on or before March 31, 2011; (ii) 2% of the principal being prepaid on or between March 31, 2011 and March 31, 2012; and (iii) 1% of the principal being prepaid on or between March 31, 2012 and September 30, 2013.

72. In connection with the Hercules Credit Facility, PolyMedix also issued a warrant which entitled Hercules to purchase 627,586 shares of its common stock on or before March 30, 2015, at a per share exercise price equal to the lesser of: (i) \$1.16; or (ii) the twenty-day volume weighted average price of PolyMedix's Common stock prior to the closing of the Hercules Credit Facility. Based on the April 5, 2012 closing of the Hercules Credit Facility, the exercise price for the PolyMedix stock based on the latter calculation is \$1.22 per share. As of the date of this filing, no shares have been issued to Hercules pursuant to the warrant.

3. The \$20 Million Equity Offering

- 73. The Company's need for funding increased dramatically as the Class Period approached. Indeed, the Phase II studies for both PMX-60056 and PMX-30063 were expected to cost significantly more than the Phase I clinical studies that were conducted in 2009 and 2010. The Company's 2011 10-K specifically notes this need for capital, stating that "all of our product candidates are in the early stages of development and *all but two of our programs are either on hold pending additional funding or being developed only to the extent they are substantially funded* by targeted grants or research contracts." The 2011 10-K goes on to note that, absent an influx of capital, PolyMedix barely had "current cash and investment balances ... sufficient to fund ... [its] operations for ... the next 12 months."
- 74. Accordingly, in April 2011, PolyMedix commenced a direct public offering of up to twenty-five million units at a purchase price of \$0.80 per unit (the "April Equity Offering").

⁷ Had the Company borrowed the additional \$4 million available to it under the Hercules Credit Facility, the warrant would have been exercisable for an additional 156,896 shares.

⁸ The April Equity Offering was made pursuant to the "shelf" registration statement filed by the Company with the SEC on March 31, 2010, which authorized the issuance of up to \$100 million worth of PolyMedix stock.

Each unit entitled the acquirer to one share of the Company's common stock and one warrant to purchase an additional one-half of a share on or before April 10, 2016, at an exercise price of \$0.80. The April Equity Offering closed on April 10, 2011, with all twenty-five million units being sold – resulting in the issuance of twenty-five million shares of PolyMedix common stock and 12.5 million warrants.

75. The Company received \$18,451,000 in net proceeds as a result of the April Equity Offering – \$3,237,000 of which was used to pay down the principal on certain of its outstanding debt obligations. As stated in an April 6, 2011 press release, the remaining proceeds from the April Equity Offering were earmarked for the continued "clinical development of PolyMedix's two lead drugs, PMX-30063 ... and PMX-60056."

4. The MidCap Financial SBIC, LP Credit Facility

- 76. While the cash from the April Equity Offering allowed the Company to continue its operations through the remainder of 2011, the Company knew additional capital would be required in order to fully fund the development of PMX-30063 as it advanced into late stage development. Indeed, the 2012 10-K noted that the Company "d[id] not currently have the funding resources necessary to carry out all of [its] planned operating activities" and would have to "seek additional funding in one or more equity or debt financings." The 2012 10-K goes on to note that the Company believes its "current cash and investment balances will fund [its] ongoing Phase II studies ... and can fund [its] operations for at least the next twelve months" (i.e. through early 2013). However, as shown herein, even this dire estimate appeared be overly optimistic.
- 77. At both the Lazard Capital Markets 8th Annual Healthcare Conference (held on November 16, 2011) and the Cowen & Company's 32nd Annual Health Care Conference (held on March 6, 2012), defendant Landekic explained how the Company came to conclude that it had adequate funding to get through the remainder of 2012. Specifically, he stated PolyMedix had "\$25 million of cash in the balance sheet" and was "burning about \$4 million a quarter"

thereby giving it "cash into early 2013." This was overstating the Company's cash flow position, as the Company's financial statements indicate that PolyMedix actually had less than \$22 million worth of liquid assets available as of the period ending December 11, 2011¹⁰ and was burning through, on average, over \$5.5 million a quarter – implying the Company had insufficient funding to survive the end of 2012.

- 78. In any event, the Company was in desperate need of an infusion of capital to give it any chance of completing development for PMX-30063. Rather than issue more equity, however, Defendants devised a plan to refinance its debt obligations under the existing Hercules Credit Facility on more favorable terms while simultaneously obtaining the additional operating capital it so desperately needed. As a result, on April 5, 2012, PolyMedix entered into a Loan and Security Agreement with MidCap Financial SBIC, LP ("MidCap") worth up to \$12 million (the "MidCap Credit Facility"). Upon execution, the Company was advanced an initial \$8 million approximately \$5.6 million of which was used to pay off the outstanding balance, unpaid interest, and prepayment penalties on the Hercules Credit Facility.
- 79. The MidCap Credit Facility has a thirty-nine-month term, carries an interest rate of 11.95%, and requires interest-only payments until January 1, 2013. Starting on February 1, 2013, the MidCap Credit Facility is to be paid down in equal monthly installments with a balloon payment consisting of all unpaid principal and interest being due and payable on July 1, 2015.
- 80. In entering into the MidCap Credit Facility, PolyMedix made certain representations and warranties to MidCap, without which, the credit facility would not have been executed. In particular, PolyMedix represented and warranted that: "(i) there have been no adverse clinical test results, of which Borrowers has been made, or reasonably should be,

⁹ Defendant Smith made similar statements at the Roth 24th Annual Growth Stock Conference held on March 12, 2012.

¹⁰ The August 2012 10-Q indicates the same, stating that PolyMedix had a "cash and investment balance[] of approximately \$12,345,000 and \$21,354,000" as of December 31, 2011.

aware, which have or could reasonably be expected to cause a Material Adverse Change, and (ii) there have been no Product recalls or voluntary Product withdrawals from any market." Thus, PolyMedix represented to MidCap in early April 2012 that it was not aware of any negative data results for its then ongoing Phase II and Phase Ib studies for PMX-60056 and then only a month later discontinued clinical trial development of PMX-60056 due to significant hypotension seen in these studies.

- 81. PolyMedix also negotiated a strict default provision in the MidCap Credit Facility that places them in default only if it voluntarily ceases clinical development of **both** PMX-60056 **and** PMX-30063 or is otherwise forced to cease development of both lead drugs by any regulatory authority. Thus, notably, PolyMedix's termination of its PMX-60056 program a month later did not result in an automatic default under the MidCap Credit Facility.
- 82. On June 11, 2012 just one month after the Company disclosed to the public and MidCap that it had discontinued its development of PMX-60056 MidCap forced PolyMedix into a First Amendment to Loan and Security Agreement with MidCap (the "Amendment"). In addition to modifying certain terms of the MidCap Credit Facility, the Amendment reduced the maximum size of the facility to \$8 million and required the Company to pay back \$1.2 million of the \$8 million it had already borrowed.
- 83. In connection with the MidCap Credit Facility, PolyMedix also issued a detachable warrant which entitles MidCap to purchase up to 161,290 shares of PolyMedix's common stock on or before April 5, 2017, at an exercise price of \$1.24 per share. As of the date of this filing, no shares have been issued to MidCap pursuant to the warrant.

¹¹ Had the Company borrowed the full \$12 million originally available to it under the MidCap Credit Facility, the warrant would have been exercisable for an additional number of shares equal to 2.5% of the amount borrowed divided by the applicable exercise price.

I. PolyMedix Gradually Shifts Its Focus from PMX-60056 to PMX-30063

84. Prior to 2011, PolyMedix had promoted PMX-60056 and PMX-30063 as its colead drug candidates. Starting in the early part of that year though, as reflected by internal personnel moves and its public statements, PolyMedix began to place its PMX-30063 program ahead of its PMX-60056 program.

1. Personnel Moves

- 85. While continuing to tout the past clinical trial results and future prospects of its PMX-60056 program to the public, the Company was making a number of internal personnel moves during the Class Period that suggest it was de-emphasizing, and possibly winding down, this clinical trial program. Most notably, in January 2011, PolyMedix demoted its longtime Chief Medical Officer and Vice President of Clinical Development Eric McAllister, who was the primary champion of the PMX-60056 program. Prior to his demotion, he had served in these positions since November 2006. Although McAllister oversaw all drug development activities in these capacities, most of his clinical trial experience was in the development of drugs designed to treat cardiovascular disorders and as a result, he focused his efforts accordingly on the PMX-60056 program. According to SEC filings, he had held clinical development positions with a number of pharmaceutical companies, including Bristol-Myers Squibb Company, Searle & Co., and Syntex Pharmaceuticals, Ltd., working primarily on the development of cardiovascularrelated drugs such as Pravochol, Capoten, Kerlone, Cardene, Calan, Teveten, and Atacand. In his new position as Vice President of Cardiovascular Clinical Development, he worked exclusively on the PMX-60056 program.
- 86. PolyMedix promoted Dr. Bozena Korczak to replace defendant McAllister as head of all drug development operations for PolyMedix in the position of the Senior Vice President, Drug Development and Chief Development Officer. Dr. Korczak's experience was in developing drugs designed to treat infectious diseases and she had worked solely on the PMX-30063 program prior to her promotion. These personnel moves required defendant McAllister to

then report to Dr. Korczak. PolyMedix quietly announced his demotion at the end of a press release dated January 24, 2011, announcing the promotion of Dr. Korczak to her new position.

87. In August 2011, PolyMedix terminated defendant McAllister without naming anyone to succeed him as head of the PMX-60056 program. In yet another personnel move indicating the Company's change in direction, PolyMedix appointed Daniel M. Jorgensen, MD, MPH to be Senior Vice President of Clinical Development and CMO, which had been vacant since Dr. McAllister's demotion eight months earlier. Like Dr. Korczak, Dr. Jorgensen's background was in the development of antibiotics and the hiring of him to lead the Company's drug development activities reflects that the Company had already decided by this time to emphasize the PMX-30063 program over the PMX-60056 program. This further demonstrates that the Company was aware at this time of the significant problems with the PMX-60056 clinical trial program, and in particular that: (i) hypotension was a serious side effect, both based on the results of the initial studies, and initial data from the then ongoing Phase II Study; and (ii) they were unable to enroll enough patients to complete the study.

2. PolyMedix's Shift in Focus to PMX-30063 Trials

- 88. Throughout most of 2011, PolyMedix had promoted its two lead drugs PMX-30063 and PMX-60056 on equal footing. At investor and medical conferences, PolyMedix billed its mission as "rational drug design combined with a rationale business model" in order to "develop novel first-of-their kind therapeutic drugs for life-threatening acute disorders" in two areas, infectious disease and acute cardiovascular. At these conferences, PolyMedix generally gave equal attention to its two clinical programs in its presentations, detailing how each drug worked and the results of the prior trials for each drug and then providing updates on the ongoing studies.
- 89. During this time period, PolyMedix's two drug compounds were at comparable stages of development. While PolyMedix was conducting the Phase II Study of the PMX-60056 in 2011, at the same time it was also conducting a Phase II study of PMX-30063. The Phase II study for PMX-30063 was expected to enroll 200 patients and required longer-term patient

assessment than the Phase II Study of PMX-60056 (up to fifteen to twenty days following administration of drug). Nevertheless, according to the Company's statements in the first half of 2011, both trials had the same projected timeline – completion by the end of 2011.

- 90. For example, on March 7, 2011, at the Cowen & Company's 31st Annual Health Care Conference, defendant Landekic stated that that PolyMedix "expect[ed] to have the final results of th[e Phase II study for PMX-30063] by the end of [2011]." Defendant Landekic devoted equal portions of this presentation to the two lead drug programs, discussing how the drugs worked, detailing the results of the prior studies, and providing updates on the current studies. At investor conferences between March and September 2011, PolyMedix provided similar presentations that gave similar levels of attention to the two drug programs.
- 91. On September 12, 2011, PolyMedix issued a press release in which it provided updates on its two lead clinical programs. In its update on PMX-60056, PolyMedix disclosed only that "[e]nrollment" for its Phase II and Phase Ib/2 was "ongoing" and that results were "expected to be completed by the end of [2011]." By contrast, the Company detailed the status of its Phase II study for PMX-30063 in greater detail. For example, the Company announced that it had added multiple new clinical sites in Europe to accelerate enrollment for this study and that because of delays in receiving regulatory approval for such sites, the Company would be delayed in announcing interim results until the end of 2011, and delayed in completing the study until the first half of 2012. Specifically, the press release states, in relevant part, that:

Results from an interim analysis will be released once data are analyzed from the first 80 patients enrolled in the trial. PolyMedix recently received clearances from European regulatory agencies which has enabled adding multiple new clinical sites in Russia and Ukraine to accelerate enrollment. Additional sites in Europe may be added later this year. As a result of longer than expected time to receive European regulatory clearances, PolyMedix anticipates announcing the interim results later this year, and expects to complete the full trial in the first half of next year.

92. Starting in November 2011, PolyMedix began to center its attention on its PMX-30063 program. The Company held an investor's conference call on November 16, 2011, to discuss the upcoming interim data results for the Phase II study for PMX-30063. During this

call, defendant Landekic detailed the status of the ongoing Phase II study, including how many patients had enrolled to date, the purpose of the interim analysis, and the specific efficacy and safety endpoints. By contrast, defendant Landekis said very little about the Phase II Study for PMX-60056, stating only that they still expected to report results for both this study and the Phase Ib/II study by the end of 2011.

- 93. On December 7, 2011, PolyMedix issued a press release and held a special investor's conference call to review the interim results from its Phase II study for PMX-30063. In the press release, PolyMedix announced positive results based on an interim analysis of the data for the eighty patients that had been enrolled to date. According to the Company, the interim data available "indicat[ed] that all dosing arms in the study were both safe and effective in treating patients with Acute Bacterial Skin and Skin Structure Infections (ABSSSI)." The press release further stated that "PolyMedix is continuing to enroll patients and expects to complete the full trial in the first half of 2012." At the conference call, defendant Landekic detailed what the data showed and the status of enrollment. At the end of the call, one of the analysts asked for an update on the Phase II Study for PMX-60056, but Landekic responded merely that "[b]oth of the 60056 studies [we]re continuing" and that PolyMedix "[would] like to keep th[e] call focused on 30063."
- 94. Further signaling the Company's change in focus to PMX-30063, on March 6, 2012, at PolyMedix's presentation at the Cowen & Company's 32nd Annual Health Care Conference, defendant Landekic stated that the mission of PolyMedix had become "revolutionizing the treatment of infectious diseases." While he did briefly tout the results of the initial studies of PMX-60056, he focused his presentation on promoting the PMX-30063 program.
- 95. At the March 6, 2012 Cowen & Company's 32nd Annual Health Care Conference, defendant Landekic also suggested that the Company was considering licensing PMX-60056 in order to fund the development of PMX-30063. Specifically, he stated that it was possible that PolyMedix would "out license world-wide rights on heptagonist to 60056 and keep

the antibodies and take 30063 to clinical trials ourselves." Similarly, at the March 11-14, 2012 Roth 24th Annual Growth Stock Conference, defendant Smith stated: "PMX-60056, that's an asset for which we may choose to license the world for in order to retain and also fund the future development of PMX-3006, and be able to further and broaden the infectious disease platform."

96. On April 23, 2012, PolyMedix announced positive final results from its Phase II clinical trial for the PMX-30063 program. According to the Company, the study for ABSSSI patients "showed all three doses to have high clinical response rates and to be safe."

V. DEFENDANTS' FALSE AND MATERIALLY MISLEADING STATEMENTS AND OMISSIONS

- A. Defendants Misrepresented that the Hypotension Seen in the Initial Studies Was Not Clinically Significant
- 97. During the Class Period, Defendants repeatedly downplayed the hypotension seen in the initial studies as "transient" and "not clinically significant" and touted it as a safe alternative to Protamine on this basis. These false and materially misleading statements include:
- (a) On March 7, 2011, PolyMedix filed the 2011 10-K signed by defendants Landekic and Smith, in which Defendants downplayed the risk of hypotension seen in Study-3:

In August 2010, we successfully completed an open label, dose titration, [heparin] reversal study (Phase 1B/2) of PMX-60056, which was conducted at a single site in the United States. *PMX-60056 met the study safety and efficacy endpoints in both the reversal of surgical levels of [heparin]* and in subsequent re-anticoagulation with [heparin] and re-reversal with PMX-60056. *PMX-60056 was well tolerated in this study, with no serious or reportable adverse events occurring. Subjects in the study experienced minimal side effects, which consisted of transient reductions in blood pressure, which were not clinically significant and were seen only at the end of some reversals when ACT was already nearing baseline after the last dose of PMX-60056.*

(b) On March 7, 2011, PolyMedix presented at the Cowen & Company 31st Annual Health Care Conference. At the conference, defendant Landekic touted the positive safety results of the initial studies, and in particular that no significant hypotension was experienced in the studies: "The drug appears to be relatively well tolerated.... [T]he conclusions from these studies were that there were no clinically meaningful or statistically significant

changes seen in blood pressure, which we believe is much better tolerated than would be with the Protamine."

- (c) On May 17, 2011, defendant Smith presented at the Noble Financial Capital Markets Seventh Annual Equity Conference. During the presentation, defendant Smith touted the results of the initial studies, stating the Company had "completed four clinical trials and met both the safety and efficacy parameters of those trials."
- (d) On May 25, 2011, PolyMedix presented at the 2011 UBS Global Specialty Pharmaceuticals Conference. During the presentation, defendant Landekic lauded the safety profile of PMX-60056 in comparison to Protamine.

Our protein [sic: Protamine] is widely used between 6 million to 8 million times per year and it's a very old and problematic drug. It's been around for more than 50 years and a lot of potential side effects, liabilities and toxicities of protamine that from our clinical results we think we found something much safer and easier to use.

- (e) On September 12, 2011, PolyMedix presented at the Rodman & Renshaw Global Investment Conference. During the presentation, defendant Landekic stated that PMX-60056 "will be safer to use" than Protamine.
- (f) The September 12, 2011 press release also continued to tout the safety and efficacy results from the initial studies, stating that "PMX- 60056 has met safety and efficacy endpoints in four clinical trials conducted to date demonstrating clinical proof of concept."
- (g) On September 19, 2011, PolyMedix presented at the 2011 UBS Global Life Sciences Conference. At this conference, defendant Landekic billed PMX-60056 as a safer alternative to Protamine for reversing heparin: "There's only one reversing agent available to do that, protamine. A drug that's been around since the 1940s. *It's a problematic drug with many toxicities and liabilities. I will show you with our clinical results, we've been able to address them.*" He went on to tout the positive safety results from the initial studies, and in particular that the drug did not present a risk of hypotension:

The drug appears well-tolerated. These are blood pressure changes in both of these studies. This is superimposing the drug versus placebo line. There's always variation including on placebo. The conclusions from both of these

studies where there are no blood pressure changes that were considered either statistically significant or clinically important.

- (h) On September 27, 2011, PolyMedix issued a press release titled, *PolyMedix Initiates Phase IB/2 Dose-Response Clinical Trial to Reverse the Anticoagulant Activity of Enoxaparin with PMX-60056*, announcing the expanded development of PMX-60056 in LMWH. In the press release, defendant Landekic touted the positive safety results of the early studies, stating that: "PMX-60056 has met safety and efficacy endpoints in four clinical trials conducted to date demonstrating clinical proof of concept. PMX-60056 is currently in a Phase 2 clinical trial in patients undergoing PCI."
- (i) On December 7, 2011, PolyMedix issued a press release entitled, PolyMedix Announces Encouraging Interim Results from Multinational Phase 2 Clinical Trial with PMX-30063 Defensin-Mimetic Antibiotic, in which it reiterated that "PMX-60056 has met safety and efficacy endpoints in four clinical trials conducted to date demonstrating clinical proof of concept."
- (j) In a January 4, 2012 press release entitled *PolyMedix Completes Enrollment in Phase 2 Trial With PMX-30063 Defensin-Mimetic Antibiotic*, the Company once again stated how "PMX-60056 has met safety and efficacy endpoints in four clinical trials conducted to date demonstrating proof of concept."
- (k) On March 6, 2012, PolyMedix presented at the Cowen & Company's 32nd Annual Health Care Conference. During the presentation, defendant Landekic made the following statements regarding PMX 30063 and 60056: "In infectious diseases, we have PMX-30063 ... and an acute cardiovascular PMX-60056, an anticoagulant reversing agent. We've shown efficacy and safety in eight completed clinical trials so far with these drugs."
- (I) On March 12, 2012, PolyMedix presented at the Roth 24th Annual Growth Stock Conference. During the presentation, defendant Smith made the following statements about PMX-60056: "A few words on the heptagonist program, right now PMX-60056 is our second Phase 2 asset.... The idea is to address the reversal of heparin and have a safer protamine for the in-patient population, for which heparin needs to be reversed."

(m) On March 13, 2012, PolyMedix filed the 2012 10-K signed by defendants Landekic and Smith with the SEC. The 2012 10-K lauded the positive safety and efficacy results from the initial studies for PMX-60056, stating:

Clinical Experiments to Date

In October 2009, we completed a single-dose Phase 1B/2 study where PMX-60056 met the study endpoints regarding safely and efficacy in permanently reversing heparin. Six healthy subjects were given 70 U/kg of heparin followed twenty minutes later with either a single dose of 0.3 mg/kg of PMX-60056 or a placebo administered intravenously. Each subject received two dosing regimens, initially with heparin and either PMX-60056 or a placebo and then, two days after the first dose, with the alternative regimen (heparin and either PMX-60056 or placebo). The anticoagulant activity of heparin was rapidly and completely reversed in all subjects receiving PMX-60056, as measured by activated partial thromboplastic time (aPTT).

In June 2010, we completed a single-dose Phase 1B/2 study where *PMX-60056* met the study endpoints regarding safety and efficacy in reversing the LMWH tinzaparin (Innohep®). Six healthy subjects were given a subcutaneous injection of tinzaparin, followed 5 and 8 hours later by two ten-minute intravenous infusions of PMX-60056 or placebo. PMX-60056 rapidly reduced anti-Xa activity (a critical clotting factor) and rapidly and completely reversed the anticoagulant action of tinzaparin, as measured by aPTT. Each subject's minimum aPTT readings after being dosed with PMX-60056 were at or near the subject's aPTT readings prior to being dosed with tinzaparin.

In August 2010, we completed a dose-ranging Phase 1B/2 clinical study where *PMX-60056 met the study endpoints regarding safety and efficacy in both the reversal of varying heparin levels, and allowing re-anticoagulation and re-reversal.* Twelve healthy subjects received either 200 U/kg or 350 U/kg of heparin, followed 20 minutes later by an initial ten-minute infusion of PMX-60056. Subjects then received additional infusions of PMX-60056 until the remaining heparin was fully reversed. Following the first reversal of heparin, a second dose of 100 U/kg of heparin was administered to achieve reanticoagulation, which was then also reversed with PMX-60056. *PMX-60056 was generally well tolerated with no serious adverse events reported during the study.*

(n) On May 1, 2012, PolyMedix hosted its 2012 Annual Shareholder Meeting during which it gave a PowerPoint presentation regarding its drugs in development. In the presentation, Defendants continued to tout the positive safety and efficacy results for both PMX-60056 and PMX-30063, stating that: "PMX-30063 and PMX-60056 were in Phase 2 clinical trial development, and specifically confirmed that, 'efficacy and safety [were] demonstrated in 8

clinical trials' and that because the drugs involved 'acute dosing' the development path was 'efficient' and 'inexpensive.'"

- 98. As shown below, Defendants' statements downplaying the risk of hypotension seen in the initial Phase I studies and touting PMX-60056 as a safe alternative to Protamine were false materially misleading, and made with scienter because, three of the six healthy male volunteers in Study-3 experienced hypotension with one experiencing such serious hypotension that he required emergency medical treatment.
- 99. Indeed, at the 2010 ASH Meeting on December 6, 2010, PolyMedix presented the results of its initial Phase I studies in connection with PMX-60056. The associated poster presentation entitled *Reversal of Heparin by Novel Synthetic Antagonist PMX-60056 Exhibits a Linear Dose-Response Relationship*, contains a section entitled "Abstract," buried in the middle of which is the following statement:
 - 350 U/kg of heparin was reversed in 6 normal volunteers, after an initial 10-minute infusion of 0.7 mg/kg PMX-60056 and subsequent smaller doses as needed to normalize ACT. Hemodynamics were unaffected until total PMX-60056 dose exceeded 1 mg/kg the initial does of 0.7 mg/kg never produced a change. When a hemodynamic effect did occur (in 3 of the 6), it was initiated by a fall in systemic vascular resistance. Only 1 of these 6 subjects had a clinically significant hypotension, which lasted 15 minutes with pressor agents and limb elevation; this subject was subsequently found to have a past history suggestive of vaso-vagal instability. The other 5 subjects had no appreciable change in blood pressure.
- 100. Nowhere in this poster does it explain which study this statement refers to. Only upon a review of all SEC filings, press releases, analyst reports, data presentations, and conference call transcripts could it be determined that this refers to Study-3.
- 101. The Company's statement in the above poster presentation that "[w]hen a hemodynamic effect did occur (in 3 of the 6), it was initiated by a fall in systemic vascular resistance," meant that three of the six volunteers experienced hypotension, or a drop in blood pressure, as a result of PMX-60056.
- 102. More importantly, an interpretation of PolyMedix's summary of the results from Study-3 reveals that at least one of the subjects experienced hypotension to such a significant

degree that emergency medical attention was required. Specifically, the Company states in the poster presentation that "[o]nly 1 of these 6 subjects had a clinically significant hypotension, which lasted 15 minutes with pressor agents and limb elevation." Pressor agents are drugs used to immediately raise arterial blood pressure in those instances where severe and dangerous hypotension levels are observed (i.e., "emergencies"). Accordingly, the fact that pressor agents were needed to remedy the hypotension observed in one of the six Study-3 volunteers demonstrates the severity of that individual's hypotensive response to PMX-60056.

103. Defendants attempted to downplay the significance of the hypotension seen in Study-3 by attributing it to the fact that the particular volunteer requiring emergency assistance in the form of pressor agents "was found to have a past history suggestive of vaso-vagal instability." However, it was improper for Defendants to disregard this subject's experience of significant hypotension for these reasons, especially given that the patients for whom this drug was designed – those undergoing PCI or CABG procedures – are more likely to suffer a vaso-vagal episode, both because their underlying cardiac systems are compromised and because the stress of undergoing the procedure, resulting in comparably significant hypotension. In other words, the fact that this particular patient experienced significant hypotension in Study-3 strongly suggests that this drug presents an unsafe risk of hypotension to individuals undergoing PCI and/or CABG procedures.

B. Defendants Misrepresented that Hypotension Could Be Completely Eliminated as a Side Effect With Appropriate Dosing

104. Both before and during the Class Period, Defendants repeatedly misrepresented that they could identify safe and effective dosages for PMX-60056. In falsely assuring investors that hypotension could be eliminated as a side effect, Defendants relied upon their unsupported findings from the initial studies that: (i) the drug can cause hypotension only if excess of the drug (over heparin) is present; and (ii) they had established a dose-response relationship whereby they could determine the precise amount needed to fully reverse a given dose of heparin. Examples of these false and materially misleading statements include:

- (a) On December 6, 2010, at the 2010 ASH Meeting, PolyMedix presented clinical data study results for PMX-60056. At the meeting, defendant McAllister reviewed trial results from a presentation titled *Reversal of Heparin by Novel Synthetic Antagonist PMX-60056 Exhibits a Linear Dose-Response Relationship*. According to the presentation's "Abstract" section: "These data suggest that measurements routinely available during cardiac surgery are sufficient for predicting a single reversing dose of PMX-60056 that will safely and effectively neutralize [heparin]-induced anticoagulation."
- (b) Finally, in the "Summary" and "Discussion" sections of the poster presentation, defendant McAllister noted:

PMX-60056 predictably, safely, and completely reverses the anticoagulation effects of high doses of [heparin] in man. Complete reversal can be obtained without adverse effect, by computing the appropriate dose using a simple linear relationship.

A linear-dose response relationship has been demonstrated in these normal subjects, enabling calculation of the appropriate dose of PMX-60056 for completely (or if desired, partially) reversing the anticoagulation produced by unfractionated heparin at high doses.

With the dose-response relationship as given here, excess (and therefore hypotension) can be completely avoided.

(c) On December 7, 2010, PolyMedix issued a press release in which the Company announced that clinical data from its Phase Ib/2 dose ranging trial clinical study with PMX-60056 was presented at the 2010 ASH Meeting on December 6, 2010. The press release stated, in part:

In a poster presentation titled, Reversal of Heparin by Novel Synthetic Antagonist PMX-60056 Exhibits A Linear Dose Response Relationship, Dr. Eric McAllister, Vice President of Clinical Development at PolyMedix, reported clinical results demonstrating that, using measurements routinely available during cardiac surgery, clinicians can accurately predict a single reversing dose of PMX-60056 that will safely and effectively neutralize the anticoagulation effects of heparin.

(d) On March 11, 2011, PolyMedix participated in the 31st Annual Cardiothoracic Surgery Symposium. In a data presentation titled, *PMX-60056 Reverses Heparin*

- *Predictability and Safely*, defendant McAllister downplayed blood pressure concerns, stating that hypotension occurred only if excess of the drug was given. Specifically, his presentation slides stated:

If it binds to heparin, it is no longer the same chemical. If this binding occurs rapidly, and ... If the binding to heparin is preferential, then ... there would be very little free drug present, so ... Hypotension should not occur. So we did a study to find out....And the beauty of this study was, it also evaluates EFFICACY!

Defendant McAllister went on to further tout the lack of hypotension seen in Study-3, and even claimed that a dose-response relationship had been established:

No hypotension occurred until heparin had been exhausted. Excess PMX-60056 initially caused a fall in total peripheral resistance; increased heart rate began; if cardiac output could not compensate, BP fell.... [From this trial, the Company concluded that] [a] dose-response curve has been worked out.

(e) On April 28, 2011, PolyMedix presented at the AHA's ATVB 2011 Scientific Sessions. During the two-hour session, defendant McAllister touted PMX-60056 as a safe alternative to Protamine that presents no risk of hypotension when the appropriate dosage is given. Specifically, the abstract and poster presentation from the conference, entitled *PMX-60056 Reversal of Heparin and LMWH Has Linear Dose-Response Due to Specific Molar Binding*, included the following statements:

Efficacy and safety have been demonstrated in 4 phase 1 trials.... [PMX-60056] can cause hypotension, like protamine in similar anticoagulation-reversal usage; but protamine reportedly has hypotensive effects on first exposure, while PMX-60056 has none unless there is drug in excess of the amount needed for heparin reversal.

- (f) In the May 17, 2011 presentation, defendant Smith stated that the major limitations of Protamine was that it "can cause serious hypotension," whereas, hypotensive effects for PMX-60056 are "believed only with excess drug" and are expected to be "more manageable than [in] protamine."
- (g) In this same presentation, defendant Smith stated PolyMedix had found a precise dose-response relationship that would enable it to identify safe and effective dosages for the drug. Specifically, he stated:

And then the last study we completed for this program is [the Phase Ib/II doseranging, safety, and efficacy study using surgical levels of heparin].... And then the third thing we wanted to learn from this study was what's, essentially what's the stoichiometry of PMX-60056. How much PMX-60056 is needed to reverse a given amount of heparin, so that we can use that calculation in order to guide dosing in Phase II. And you can see here on this graph that not only is the dosing linear, but it's linear at the correlation coefficient or R-squared of .96. So dosing in Phase II should be highly predictive and easy to calculate.

(h) On May 25, 2011, PolyMedix presented at the 2011 UBS Global Specialty Pharmaceuticals Conference. During the presentation, defendant Landekic claimed that PolyMedix had figured out a precise dose-response relationship that would allow it to prescribe safe and effective dosages:

Most importantly, this study established the dose-response correlation, and the relationship is very, very tight. How much of our drug you need to give is an extremely tied into relationship of how much heparin you want to reverse. The correlation coefficient r^2, is greater than 0.96. So very, very predictable. It's very again unusual in medicine, there's such a titrate-response correlation. This makes the drug very straightforward to give, very easy to dose, you don't have to titrate. And if one wants to dial-in a particular amount of heparin reversal if one wants to reverse half or three-quarters the amount of heparin, it can be very, very easily be done with such a tight dose-response correlation

(i) On September 12, 2011, PolyMedix presented at the Rodman & Renshaw Global Investment Conference. During the presentation, defendant Landekic stated that PMX-60056 "will be safer to use" than Protamine. Defendant Landekic went on to say at the conference that a dose-response relationship had been worked out and as a result, it would be easy to determine the appropriate dose. Specifically, he stated:

And most importantly what's the dose response correlation? What's the relationship between how much drug you have to give for how much heparin you want to reverse? You can see here it's a very, very linear relationship, it's very precise and highly predictable relationship of how much drug you have to give. This should make this drug very easy, very straightforward, very simple to use. If a surgeon wants to reverse all the heparin, fully normalize clotting time he knows what dose to give. If he wants to reverse part of it to maintain some [Brilacidin] coagulation, he knows exactly how much to give as well. You can dial-in the precise amount of anticoagulation reversal.

(j) At the 2011 UBS Global Life Sciences Conference, Landekic further claimed that PolyMedix had determined an exact dose-response correlation that would make it easy to identify appropriate doses for PMX-60056:

And then the last efficacy study completed was a more complex dose ranging study, which showed several important things. First, the ability to reverse the highest doses of heparin approved for use in people....

Second, even more important question answered here was the ability to reheparinize and rereverse....

And then most importantly, what's the dose response correlation? How predictable is this drug to use? And the answer is very. The relationship between how much heparin do you want to reverse and how much drug you have to give is very tight.... It's a very, very linear relationship. This makes it very easy to predict exactly how much drug you need to give for how much heparin do you want to reverse.

105. Defendants' statements that it could completely eliminate hypotension as a side effect were false, materially misleading, and made with scienter because, as shown below, they were wholly unfounded based on the scope and the results of the initial studies. In falsely assuring investors that hypotension could be eliminated as a side effect, Defendants relied upon their reported findings that: (i) the drug can cause hypotension only if excess of the drug (over heparin) is present; and (ii) it had established a dose-response relationship. As shown below, Defendants had not conducted adequate studies to make these underlying claims and therefore their conclusion that they could identify hypotension-safe dosages of PMX-60056 was false and materially misleading.

1. Defendants Lacked any Reasonable Basis for Concluding that it had Identified a Precise Dose-Response Relationship

- 106. Based on FDA guidelines, the Company could not conclude that it had established a precise dose-response relationship based on the scope and results of the initial studies.
- 107. The FDA has adopted the ICH¹² Harmonised Tripartite Guideline entitled *Dose-Response Information to Support Drug Registration* as its authoritative guideline for assessing and using dose-response information in clinical trials. According to the ICH guidelines,

¹² ICH refers to the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

assessment of dose-response is an integral component of drug development and is necessary to determine safe and effective dosages. This publication further states that it is important to test subjects at a "wide range of doses" and dosing intervals in order to determine a tight dose-response relationship. In addition, it is important to obtain dose-response data from patients of different sizes, genders, ages, and those for whom the drug is designed in order to ascertain an appropriate dose-response relationship

- 108. Based on the foregoing, it is clear that PolyMedix's initial studies were inadequate to establish a precise dose-response relationship for purposes of identifying a safe and efficacious dosage of PMX-60056 for patients. Indeed, no accurate dose-response relationship could have been established in connection with PMX-60056 given the fact that: (i) PMX-60056 was given only to men and no women in the initial studies; (ii) the dosing amounts were not sufficiently varied in the studies; (iii) the drug infusion times (speed of delivery) was not varied at all, as it was given in ten minute infusions times in each study; and (iv) the drug was given only to healthy patients.
- 109. In addition, the Company did not conduct enough studies with a sufficient number of subjects to validly determine the dose-response relationship. It conducted only two studies in which the drug was given to reverse heparin and of these studies, only one was used to test the amount of the drug needed to safety and effectively reverse surgical levels of heparin. In Study-3, they administered a single starting dose to only six subjects and then added additional amounts until full reversal was achieved in each subject. This trial design was insufficient for determining a tight dose-response relationship because it could not be determined at which dosing levels, if any, the heparin was both safely and effectively reversed in these subjects.
- 110. At the time it made statements that it had found a precise dose-response relationship, PolyMedix was aware that it had not sufficiently varied the dosing intervals in order to determine a precise dose-response relationship. This is reflected by the fact that, as outlined in paragraph 31, PolyMedix stated its intention to conduct a follow-up study to prolong the infusion times (to twenty or thirty minutes) in order to further study the relationship between dose and

hypotensive response. However, as shown herein, PolyMedix never, in fact, conducted any such study before claiming to have found a dose-response relationship and moving on to Phase II testing.

established in its May 10, 2012 press release announcing the discontinuation of its PMX-60056 program. Specifically, the Company stated its belief that the hypotension observed during the clinical development process "could be addressed with PMX-60056 being delivered in a larger volume over a longer infusion time." The fact that PolyMedix was stating in May 2012, after completing both the initial trials and entering into Phase II testing, that it needed to further tinker with the dosing amounts and timing intervals in order to determine safe and effective dosages for PMX-60056 conclusively demonstrates that a precise dose-response relationship had not been identified.

2. Defendants Lacked any Reasonable Basis for Concluding that Hypotension was the Sole Result of Excess PMX-60056

- 112. As discussed herein, PolyMedix repeatedly assured investors that the only circumstances under which use of PMX-60056 would result in hypotension is when excess of the drug is given. Based on this purported finding, combined with its claim to have found a precise dose-response relationship, Defendants wrongfully concluded that all hypotension could be avoided by proper dosing. Based on the limited scope and parameters of the initial studies, however, it was unreasonable for PolyMedix to conclude that excess PMX-60056 was the only possible cause of hypotension in subjects receiving the drug.
- 113. Especially considering that, in total, only eighteen male healthy volunteers received PMX-60056 in the two initial studies in which PMX-60056 was given to reverse heparin (six in Study-2, and twelve in Study-3).
- 114. PolyMedix should have tested PMX-60056 on the patients for whom the drug was designed before concluding that excess drug was the sole cause of this side effect. As stated herein, PMX-60056 was developed for patients with coronary heart disease who are undergoing

PCI and CABG procedures. As a result of the underlying conditions which resulted in them needing surgery, patients undergoing these procedures absorb, distribute, and metabolize drugs differently than healthy subjects and, as a result, may have different responses to the drug. As a result of these potential pharmacokinetic differences, it is necessary to test the drug in actual patients before definitive conclusions can be made as to whether, and under what circumstances, the drug can cause hypotension. It is particularly important for patients undergoing cardiacrelated surgeries to be tested with PMX-60056 before making this determination because, as stated above, they are more likely to suffer from instability than healthy subjects given their already compromised cardiac systems and the stress of undergoing a PCI procedure in general. Indeed, the fact that the one subject in Study-3 who experienced significant hypotension appeared to have a history of instability suggests that PMX-60056 may cause similar hypotensive responses in similarly unstable patients (including those undergoing PCI and/or CABG procedures). In addition, women should have also been tested before jumping to the conclusion that hypotension could be eliminated by appropriate dosing because they may also have a different pharmacokinetic response to the drug than men.

- 115. Without having tested the drug on unhealthy patients and women, Defendants could not definitively rule out all other causes of hypotension. The fact that hypotension may have been observed in testing where excess PMX-60056 may have been present *does not* mean that the only circumstance in which hypotension can result is the presence of excess drug. Defendants knew this but made the unfounded claims that, unlike Protamine, only excess of the drug causes hypotension in order to promote it as a safer version of Protamine and allay any concerns about hypotension as it moved forward into Phase II testing.
 - C. Defendants Misled Investors into Believing PMX-60056 Was Safe and Did Not Present a Risk of Hypotension While Withholding from Them Negative Test Results for Their Phase II Study Showing a High Risk of Hypotension
- 116. Between September 2011 and May 2012, Defendants made a series of misleading statements touting the positive safety and efficacy results for the initial studies of PMX-60056, and in particular downplaying the risk of hypotension, while they were aware of initial data

results for the then ongoing Phase II Study showing a significant and unsafe risk of hypotension for PCI patients who receive the drug. These materially misleading statements include:

- (a) On September 27, 2011, PolyMedix issued a press release entitled, *PolyMedix Initiates Phase IB/2 Dose-Response Clinical Trial to Reverse the Anticoagulant Activity of Enoxaparin with PMX-60056*, announcing the expanded development of PMX-60056 in LMWH. In the press release, defendant Landekic touted the positive safety results of the early studies, stating that "PMX-60056 has met safety and efficacy endpoints in four clinical trials conducted to date demonstrating clinical proof of concept. PMX-60056 is currently in a Phase II clinical trial in patients undergoing PCI."
- (b) On November 16, 2011, PolyMedix presented at the Lazard Capital Markets 8th Annual Healthcare Conference. At this conference, defendant Landekic touted the positive safety and efficacy results from the initial studies and disclosed that it had determined a precise dose-response correlation that enabled it to determine safe and effective dosages for patients:

The first 4 clinical studies including 3 efficacy studies. I'll just briefly mention what we found in these studies. We found that we can very reliably and completely reverse heparin with a single dose.... And then most importantly, the drug is very predictable to use, a very tight linear-dose response correlations. The relationship between how much drug you have to give and how much heparin you want to reverse is a very, very tight relationship.

(c) On December 6, 2011, PolyMedix issued a press release titled, *PolyMedix Launches New Website*, announcing the launch of a redesigned website. According to the press release "PMX-60056 has met safety and efficacy endpoints in four clinical trials conducted to date demonstrating clinical proof of concept." The next day, PolyMedix issued another press release titled, *PolyMedix Announces Encouraging Interim Results from Multinational Phase 2 Clinical Trial with PMX-30063 Defensin-Mimetic Antibiotic*. In addition to announcing the interim analysis of its Phase II study for PMX-30063, the December 7, 2011 press release briefly referenced the PMX-60056 program, reiterating that "PMX-60056 has met safety and efficacy endpoints in four clinical trials conducted to date demonstrating clinical proof of concept."

Finally, in a January 4, 2012 press release entitled *PolyMedix Completes Enrollment in Phase 2 Trial With PMX-30063 Defensin-Mimetic Antibiotic*, the Company once again stated how "PMX-60056 has met safety and efficacy endpoints in four clinical trials conducted to date demonstrating proof of concept."

(d) On March 6, 2012, PolyMedix presented at the Cowen & Company 32nd Annual Health Care Conference. During the presentation, defendant Landekic made the following statements regarding PMX-30063 and PMX-60056:

In infectious diseases, we have PMX-30063 ... and an acute cardiovascular PMX-60056, an anticoagulant reversing agent.

We've shown efficacy and safety in eight completed clinical trials so far with these drugs. With both of these drugs, we have products that address huge unmet medical needs and major market opportunities and are also very efficient inexpensive development paths.

- (e) On March 12, 2012, PolyMedix presented at the Roth 24th Annual Growth Stock Conference. During the presentation, defendant Smith made the following statements about PMX-60056: "A few words on the heptagonist program, right now PMX-60056 is our second Phase 2 asset.... The idea is to address the reversal of heparin and have a safer protamine for the in-patient population, for which heparin needs to be reversed."
- (f) On March 13, 2012, PolyMedix filed the 2012 10-K signed by defendants Landekic and Smith with the SEC. The 2012 10-K lauded the positive safety and efficacy results from the initial studies for PMX-60056, stating:

Clinical Experiments to Date

In October 2009, we completed a single-dose Phase 1B/2 study where PMX-60056 met the study endpoints regarding safely and efficacy in permanently reversing heparin. Six healthy subjects were given 70 U/kg of heparin followed twenty minutes later with either a single dose of 0.3 mg/kg of PMX-60056 or a placebo administered intravenously. Each subject received two dosing regimens, initially with heparin and either PMX-60056 or a placebo and then, two days after the first dose, with the alternative regimen (heparin and either PMX-60056 or placebo). The anticoagulant activity of heparin was rapidly and completely reversed in all subjects receiving PMX-60056, as measured by activated partial thromboplastic time (aPTT).

In June 2010, we completed a single-dose Phase 1B/2 study where PMX-60056 met the study endpoints regarding safety and efficacy in reversing the LMWH

tinzaparin (Innohep®). Six healthy subjects were given a subcutaneous injection of tinzaparin, followed 5 and 8 hours later by two ten-minute intravenous infusions of PMX-60056 or placebo. PMX-60056 rapidly reduced anti-Xa activity (a critical clotting factor) and rapidly and completely reversed the anticoagulant action of tinzaparin, as measured by aPTT. Each subject's minimum aPTT readings after being dosed with PMX-60056 were at or near the subject's aPTT readings prior to being dosed with tinzaparin.

In August 2010, we completed a dose-ranging Phase 1B/2 clinical study where *PMX-60056 met the study endpoints regarding safety and efficacy in both the reversal of varying heparin levels, and allowing re-anticoagulation and re-reversal.* Twelve healthy subjects received either 200 U/kg or 350 U/kg of heparin, followed 20 minutes later by an initial ten-minute infusion of PMX-60056. Subjects then received additional infusions of PMX-60056 until the remaining heparin was fully reversed. Following the first reversal of heparin, a second dose of 100 U/kg of heparin was administered to achieve reanticoagulation, which was then also reversed with PMX-60056. *PMX-60056 was generally well tolerated with no serious adverse events reported during the study.*

- (g) On May 1, 2012, PolyMedix hosted its 2012 Annual Shareholder Meeting during which it gave a PowerPoint presentation regarding its drugs in development. In the presentation, Defendants continued to tout the positive safety and efficacy results for both PMX-60056 and PMX-30063, stating that PMX-30063 and PMX-60056 were in Phase II clinical trial development, and specifically confirmed that, "efficacy and safety [were] demonstrated in 8 clinical trials" and that because the drugs involved "acute dosing" the development path was "efficient" and "inexpensive."
- 117. Defendants Landekic's statements touting the positive safety and efficacy results for the initial studies of PMX-60056, and in particular promoting PMX-60056 as a safer drug than Protamine due to the reported lack of hypotension seen in the initial studies, were incomplete and materially misleading because at the time these statements (between September 2011 and May 2012) they were aware of, and failed to disclose, initial data received from the Phase II Study demonstrating a significant and unsafe risk of hypotension associated with the use of PMX-60056 in patients undergoing PCI procedures.
 - D. Defendants Misled Investors into Believing that the Phase II Study Was Proceeding as Planned and on Track to Be Completed by the End of 2011
- 118. Between September and December 2011, Defendants misled the investing public into believing that the Phase II Study was proceeding smoothly and would be completed by the

end of the year. Even between January and May 2012, Defendants continued to mislead investors into believing that the Phase II Study was progressing without difficulty and would be completed shortly. Examples of Defendants' materially misleading statements include:

(a) On September 12, 2011, PolyMedix issued a press release announcing updates on the lead clinical programs. In regards to clinical development for PMX-60056, the press release stated, in part:

Earlier this year PolyMedix initiated a Phase 2 clinical trial to evaluate the safety and efficacy of PMX-60056 in reversing heparin in patients undergoing Percutaneous Coronary Intervention (PCI) procedures. This multi-center trial is designed to enroll up to 40 patients in the United States. All patients in the trial will receive PMX-60056 by intravenous infusion. Enrollment is on-going and the trial is expected to be completed by the end of this year.

(b) On September 12, 2011, at PolyMedix's presentation at the Rodman & Renshaw Global Investment Conference, defendant Landekic discussed the status of the then ongoing Phase II Study, stating:

Earlier this year we started a Phase 2 study in PCI, and angioplasties and stent placements. The goal of the study is to look at [safety], of course, in cardiac compromised patients and efficacy reversal of heparin with a single injection of 656. We expect to complete this study by the end of this year.... So, to wrap up over the next two months we have multiple clinical events we can look forward to, two clinical studies with 60056, completing the Phase 2 PCI study and completing another efficacy study reversal of [Lominox]. 30062, the interium analysis from our ongoing Phase 2 study, completing the entire study and refunded to the Phase 2 study as well.

So multiple clinical events in the next 6 months, so a lot of clinical milestones coming up.

(c) On November 16, 2011, PolyMedix presented at the Lazard Capital Markets 8th Annual Healthcare Conference. During the presentation, defendant Landekic updated investors on the status of the then ongoing Phase II study, stating repeatedly that the trial was on track to be completed by the end of 2011:

We have 2 efficacy studies currently underway. We have a Phase II study underway in TCI [sic: PCI], reversal of heparin, following cardiac catheterizations and stent placements, and the second efficacy study underway for reversal of enoxaparin, the low molecular weight heparin Lovenox. And in the coming weeks and coming months, we expect to have results including by the end of this year in these ongoing studies as well.... And do antagonist clinical trials [refers to

Phase II Study for PMX-60056], the antagonist date is expected by the end of the year as well. So multiple efficacy events coming up in the near future.

- (d) During a December 7, 2011 conference call with investors, the media, and financial analysts, defendant Landekic was evasive in response to inquiries regarding the Phase II Study for PMX-60056. Indeed, when directly asked whether there was "[an]y update ... on 56's enrollment," defendant Landekic did not indicate that there were any problems, but rather stated merely that "[b]oth of the 60056 studies are continuing, but in the interest of time, we'd like to keep this call focused on 30063."
- (e) On January 4, 2012, PolyMedix issued another press release in which it continued to tout the results from the prior studies and merely stated that the Phase II Study was ongoing and did not indicate in any way that it was running into any problems with it. Specifically, the press release stated the following with respect to PMX-60056: "PMX-60056 has met safety and efficacy endpoints in four clinical trials conducted to date demonstrating proof of concept. PMX-60056 is currently in a Phase 2 clinical trial in patients undergoing PCI, and in a Phase 1B/2 dose ranging clinical trial with the LMWH enoxaparin."
- (f) On March 5, 2012, PolyMedix issued a press release stating that "PMX-60056 is currently in Phase 2 clinical trial in patients undergoing PCI, and in a Phase IB/2 dose ranging clinical trial with the LMWH enoxaparin." Again the press release did not indicate that PolyMedix was encountering any problems or delays with the study.
- Conference, defendant Landekic announced that PolyMedix "expect[ed] to complete" both its Phase II and Phase Ib/II studies "in the first half of [2012]," defendant Landekic went on to imply that there were no issues with the Phase II Study for PMX-60056, noting that the Company was "laser focused on getting 30063 and 60056 through the clinic and to the market" and reiterating that the results of the Phase II Study were "clinical milestones" in the development of PMX-60056.

- (h) On March 12, 2012, defendant Smith reiterated that PolyMedix's Phase II and Phase Ib/2 studies were ongoing and that they expected "to read out" the results for these studies the "first half of [2012]."
- (i) In the 2012 10-K, PolyMedix provided the same deadline for completion of the Phase II Study, stating "[f]inal results from the study are expected during the first half of 2012."
- (j) In an April 10, 2012 press release discussing its strategically timed debt restructuring, the Company stated that it was currently in Phase II and Phase Ib/2 trials and did not indicate that the studies were delayed or that they were encountering any problems at all.
- 119. Similarly, on May 1, 2012, just nine days before the Company pulled the plug on the PMX-60056 program, PolyMedix continued to create the false impression that its Phase II and Phase Ib/2 studies were proceeding smoothly and would be completed soon. PolyMedix's presentation stated that PMX-60056 was in Phase II clinical trial development and that "efficacy and safety" had been "demonstrated" in its prior "clinical trials." The presentation even touted the development path of PMX-60056 as "efficient" and "inexpensive."
- 120. Defendants' statements that the Phase II Study was on track to be completed by the end of 2011 were false, materially misleading, and incomplete because Defendants knew, or recklessly disregarded, and failed to disclose, the fact that they were having significant problems with the study, and in particular enrolling patients, that were causing significant delays to the trial and jeopardizing its ability to complete it at all. Similarly, Defendants' statements between January and May 2012 in which it misled investors into believing that the study was proceeding smoothly and would be completed within a few months, were false, materially, misleading, incomplete because Defendants knew or recklessly disregarded, and failed to disclose, the fact that they were having significant problems with the study, and in particular enrolling patients, that were causing significant delays to the trial and jeopardizing its ability to complete it at all.
- (a) Specifically, as of the date the PMX-60056 clinical trial program was discontinued, PolyMedix had enrolled only seventeen of the forty patients needed to complete

the Phase II Study and could not reasonably expect to complete the study for a long time thereafter, if at all. This enrollment issue had caused, and would have continued to cause, substantial delays to the study even if it had not been discontinued due to hypotension issues. The fact that the study was experiencing such substantial delay was material to investors because the timelines for completing clinical trials indicate how close the drug is to becoming commercially viable. In this case, the Company's projected completion date for this particular study was particularly material given that the Company had cited it as an important clinical milestone and, even more importantly, given the Company's deteriorating financial condition. With the Company running out of money for its clinical trial programs, the substantial delay meant that the Company would likely not have sufficient funding to complete the study at all. Given that the FDA had required PolyMedix to conduct the PCI study as a necessary step towards further clinical development of the drug, even if serious hypotension had not been found in the Phase II Study, PolyMedix's apparent inability to timely complete this study due to the lack of enrollment would have likely resulted in the termination of the program anyway.

VI. THE TRUTH IS REVEALED

121. On May 10, 2012, PolyMedix issued a press release disclosing for the first time to investors that the Company "decided to stop enrollment in both clinical trials due to observations of reductions in blood pressure." In the May 2012 10-Q, PolyMedix also told investors that it "will be focused on more advanced clinical trials and exploration of broader potential uses for PMX-30063...." The May 2012 10-Q stated:

In May, 2012 we stopped enrollment in our two clinical trials for PMX-60056; a Phase 2 clinical trial for reversing the anticoagulant activity of unfractionated heparin (UFH) in patients undergoing percutaneous coronary intervention procedures and a Phase 1B/2 clinical trial for reversing the anticoagulant activity of the low molecular weight heparin enoxaparin in healthy volunteers. While PMX-60056 showed activity in neutralizing UFH and enoxaparin as measured by activated clotting time (ACT) and factor Xa inhibition, respectively, we have stopped enrollment in both clinical trials due to blood pressure reductions. We believe it may be possible to address these blood pressure reductions, which may include delivering PMX-60056 over longer infusion times, and with formulation volume modifications.

We do not have any plans to conduct additional clinical studies on our own with PMX-60056, but rather plan to seek a strategic partner to further develop our cardiovascular program. Our future internal development efforts will be focused on more advanced clinical trials and exploration of broader potential uses for PMX-30063 and other defensin-mimetics.

- 122. In addition, during this same time period, investors learned that PolyMedix was running into significant problems with the study. Specifically, according to documents available on the ClinicalTrials.gov website, a registry and results database of clinical studies, as of May 16, 2012, PolyMedix had enrolled only seventeen of the forty patients needed for the study and were not close to completing it.
- 123. When the true state of PMX-60056's clinical development and adverse side effects became public, PolyMedix's shares sank from a closing pricing of \$0.59 on May 10, 2012, to a closing price of \$0.36 at the end of the day on May 11, 2012. This amounted to a single-day decline of nearly 29% on volume of over 6.7 million shares.
- 124. As a result of Defendants' false statements, PolyMedix's stock traded at artificially inflated levels during the Class Period. However, after the above revelations seeped into the market, the Company's shares were hammered by massive sales, sending them down over 74% from the Class Period high.

VII. LOSS CAUSATION

125. During the Class Period, as detailed herein, the Defendants made false and materially misleading statements and engaged in a scheme to deceive the market. Defendants' course of conduct artificially inflated the price of PolyMedix securities and operated as a fraud or deceit on Class Period purchasers of PolyMedix securities by misrepresenting the Company's business and prospects. Later, when Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of PolyMedix securities fell precipitously, as the prior artificial inflation came out of the price over time. As a result of their purchases of PolyMedix securities during the Class Period, Plaintiff and other members of the Class suffered economic loss, i.e., damages, under the federal securities laws.

VIII. DEFENDANTS ACTED WITH SCIENTER

- 126. Defendants substantially participated and/or acquiesced in the violations of federal securities laws alleged herein to have taken place. Indeed, Defendants acted with scienter in that they knew or recklessly disregarded the fact: (i) that the statements and documents made/disseminated by them in the name of the Company were false, materially misleading, and/or omitted certain material information; and (ii) that such statements/documents would be disseminated to, and relied upon by, the investing public.
- 127. Specifically, as officers and directors of the Company, Defendants controlled the content of PolyMedix's press releases, SEC filings, communications with analysts, and calls with investors. Accordingly, they had the opportunity to (and did) knowingly falsify and/or limit the information that reached the public concerning the Company. As a result, investors were misled as to the safety and clinical trial progress of PMX-60056 during the Class Period.
- 128. As detailed herein, Defendants intentionally or recklessly disseminated the false and/or misleading statements identified above (*see* Section V) in order to, among other things, conceal the significant hypotension issues associated with PMX-60056 and the difficulty of enrolling patients in its Phase II Study. By doing so, Defendants bought themselves time to obtain the additional financing necessary to continue the development of PMX-30063 and PolyMedix's other pipeline products financing which may have been inaccessible had the truth about the safety and clinical trial progress of PMX-60056 been timely revealed. In addition to ensuring the continued operation of the Company, Defendants' misconduct also served to guarantee that they would continue in their lucrative positions as officers and directors of PolyMedix.

A. Defendants Knew, or Recklessly Disregarded the Fact that Their Statements Were Materially Misleading, Incomplete, and/or False

129. Defendants are well-educated, experienced players in the biotech industry who are more than capable of interpreting the results of the Company's clinical trials, understanding the implications and seriousness of the adverse side effects and events observed during those

trials, and communicating the results of those trials accurately. As such, they knew or recklessly disregarded the fact that the statements made to the public during the Class Period (which are identified above in Section V) were false and/or materially misleading.

- 130. More specifically, as shown below, Defendants knew or recklessly disregarded that each of the above statements was false and/or misleading:
- (a) First, Defendants were aware or recklessly disregarded the falsity of their statements that the hypotension seen in the initial studies was not significant, as shown by the fact that they had prepared a poster presentation for the 2010 ASH Meeting on December 6, 2010, which disclosed that, in fact, three of the six subjects experienced hypotension in Study-3 with one subject experiencing such significant hypotension that he required emergency medical treatment. In addition, as stated above, based on their positions within the Company and their expertise and experience in drug development, Defendants were capable of interpreting the safety results of the initial trials, and in particular understood the implications and significance of the hypotension issue.
- (b) Second, Defendants were aware or recklessly disregarded that their statements that the minimal hypotension seen in the initial studies could be completely eliminated with appropriate dosing were false and materially misleading. As detailed in section V.B.2, Defendants' statements that it could identify dosages without any risk of hypotension was predicated on unsupported assertions that only excess of the drug caused hypotension and that it had discovered a tight dose-response relationship. Based on their positions within the Company and their expertise and experience in drug development, Defendants understood both the parameters and results of the initial trials and the implications and seriousness of the hypotension issue. Accordingly, Defendants knew or recklessly disregarded that the above statements were unfounded based on the results of the initial studies. In particular, upon the completion of Study-1, the Company cited the need, and stated its intention, to conduct a follow-up study in which it would vary the dose intervals in order to explore the hypotension issue and establish a dose-response relationship. But, the Company never, in fact, conducted any such

study, which demonstrates that Defendants were aware that they had not obtained all necessary dose response in order to establish a tight relationship.

- (c) Third, Defendants were aware or disregarded that their statements between September 2011 and May 2012 in which they touted the positive safety and efficacy results from the initial studies and in particular the lack of risk of hypotension were false, incomplete, and misleading. As shown herein, these statements were false, materially misleading, and incomplete based on the fact that during this time period PolyMedix was aware of, and failed to disclose, initial data from the then ongoing Phase II Study showing that the drug presented a high risk of hypotension in patients undergoing PCI procedures. That Defendants knowingly or recklessly withheld this information from the public during this time period can be inferred from the following facts:
- (i) As discussed in section IV.G.5, throughout 2011, including as late as November 16, 2011, PolyMedix was consistently informing investors that results for the study would be available by the end of 2011. The fact that PolyMedix was stating that they were on the verge of completing the study a mere six weeks before the end of the year strongly suggests that they had sufficient data (or at least what they believed was sufficient data) to report on by this time.
- (ii) As discussed in sections IV.D, IV.G, by May 2012, the Phase II Study had been ongoing for fifteen months, which was well past its projected completion date and far longer than the timelines for the previous three studies, each of which had been completed and reported on in six months or less.
- (iii) As discussed in section IV.6, the Company had continually touted how quick and expensive it was to conduct trials for PMX-60056 and that they could obtain statistically significant results after testing it on only a few patients. The Phase II and Phase Ib/2 studies, like the prior studies for PMX-60056, involved giving the patients single doses and then testing their blood pressure immediately thereafter to determine whether they had hypotension.

- (iv) Given that the primary safety endpoint for this study was examining patients for hypotension and given the ease and speed of gathering and analyzing blood pressure data, the Company would have been in possession of the hypotension results for the participating patients immediately after testing.
- (v) As discussed in section IV.G, at no time did the Company indicate that it was encountering any problems with the study that would cause a delay in reporting results or completing it. Even in their May 2012 press release (in which they announced they were discontinuing development of PMX-60056), they did not disclose that they had been delayed at all in receiving or analyzing test results. By contrast, when PolyMedix experienced delays to its Phase II study for PMX-30063, it fully and timely disclosed the nature of the delay and revised the projected completion dates.
- (vi) As discussed in sections IV.5, IV.I.2, Defendants' failure to provide interim results for this study at any point during this time period suggests they had received negative test results that they did not want to disclose to the market. By contrast, when they received positive interim results for their other drug PMX-30063 during this time period (in December 2011), even though enrollment was still ongoing, they did publicly and promptly disclose the interim data.
- (vii) As discussed in section IV.I.1, starting in early 2011 and continuing throughout the year, PolyMedix made a number of personnel moves that suggested they were winding down their PMX-60056 program and shifting their focus to their PMX-30063 program. Most notably, PolyMedix first demoted defendant McAllister (whose led the on PMX-60056 program) from Chief Medical Officer to head of the PMX-60056 program in early 2011 and then later (in August 2011) terminated him without apparently naming a replacement. In his place PolyMedix promoted and hired executives with expertise and backgrounds in development of antibiotics to lead the Company's drug development operations, which suggests that PolyMedix had decided to focus its development efforts on PMX-30063 well before they announced the discontinuation of its PMX-60056 clinical trial program.

- (viii) As discussed in sections IV.5, IV.I.2, as 2011 went along, PolyMedix made fewer and fewer public statements about PMX-60056 (and disclosed less and less about the drug in those statements) to the medical and investor communities. By contrast, PolyMedix increasingly focused more attention on its PMX-30063 program at medical and investor conferences and in its SEC filings.
- (ix) As discussed in sections IV.I.2, IV.G.6, the timing of its announcement that it was shutting down its PMX-60056 program suggests that Defendants delayed in reporting to the public the negative data results for the study. In particular, the fact that the Company released positive data results for its Phase II PMX-30063 program only weeks before announcing the termination of its PMX-60056 program suggests that the Company was hoping to demonstrate the viability of its PMX-30063 program and create positive momentum for the Company to lessen the negative fallout of subsequently disclosing the end of its PMX-60056 program. In addition, the Company timed its disclosure of the suspension of the PMX-60056 program to coincide with its 10-Q filing as a further attempt to quietly disclose the bad news.
- (x) As discussed in section IV.H.4, in entering into its loan agreement with MidCap, PolyMedix misrepresented that there were no adverse issues or potentially adverse issues with its PMX-60056 program, when, in fact, they were seeing hypotension issues among participating patients in the Phase II and Phase Ib/2 studies. Given that they shut down the clinical trial program only a month after making this representation to MidCap demonstrates that they deceived MidCap. In addition, the fact that after PolyMedix announced it was discontinuing its PMX-60056 program, MidCap forced PolyMedix to amend the agreement and pay back a portion of the loan proceeds strongly suggests that MidCap believed that it, along with the public, had been misled about the safety and clinical trial programs of the PMX-60056 program.
- (d) Fourth, Defendants were aware or disregarded that their statements between September 2011 and May 2012 in which they assured investors that the study was

proceeding smoothly and remained on schedule to be completed were false, materially misleading, and incomplete. Such statements were false, materially misleading, and incomplete based on the fact that during this time period Defendants were aware of or had recklessly disregarded, and failed to disclose, the fact that they were encountering significant problems with the study, and in particular enrolling patients, which caused substantial delay to the trial and jeopardized their ability to complete it all. Given their positions within the Company and the fact that PMX-60056 was one of their two leading clinical trial programs, Defendants were clearly aware during this timeframe of the status of its critical Phase II Study, and in particular the fact that it was having such significant problems enrolling patients.

B. Defendants Fraudulent Conduct Was Motivated by the Need to Obtain Additional Funding in Order to Continue the Development of PMX-30063

131. Defendants were aware of the hypotension issues affecting PMX-60056's long-term development and commercialization prospects well before the Company announced it was discontinuing testing thereof in May 2012. However, rather than disclose this material information to investors, Defendants delayed its release until they had obtained much needed financing, and on the best available terms, thereby ensuring the Company would have the resources necessary to continue developing PMX-30063 and its other product candidates. Only after it had: (i) secured such financing; and (ii) released positive results for its Phase II study in connection with PMX-30063 did PolyMedix reluctantly (and in direct response to investor pressure for an update) announce that it was discontinuing development of PMX-60056 due to hypotension concerns. This announcement caused the per share price of PolyMedix stock to fall over 74% from the Class Period high – costing investors millions of dollars.

1. The Company's Need for Additional Funding and the Difficulty of Accessing the Debt and Equity Markets During the Class Period

132. PolyMedix has not had any sales revenue since its inception in 2002. Accordingly, the Company relies almost exclusively on the debt and equity markets to fund its ongoing research and development activities. The Company's ability to access these funding sources was never as important as it was during the Class Period. With insufficient funds to

conduct its ongoing clinical trials for even 12 months, PolyMedix needed an extensive influx of capital during the Class Period if it ever hoped to bring one of its drugs to market. This need for financing, combined with the state of the credit and capital markets at the time, posed a serious threat to the Company's ability to continue as a going concern.

- 133. Given that PolyMedix had only two viable product candidates in testing during the Class Period, any negative news concerning the development and future prospects of either PMX-60056 or PMX-30063 would have had a detrimental effect on the trading price of its stock and, consequently, the Company's ability to access the equity markets on favorable terms, if at all. Accordingly, Defendants downplayed the risk of hypotension seen in the initial Phase I studies and misled the market into thinking the Phase II Study was proceeding as planned. By doing so, Defendants were able to keep the Company's stock trading at an artificially inflated price, thereby ensuring that it could obtain additional financing on favorable terms for the future development of PMX-30063 and the other drug compounds in its product pipeline.
- 134. As a result of this market deception, Defendants were able to secure over \$25 million of financing during the Class Period. Had Defendants not made the false and materially misleading statements identified above (*see* Section V), they would not have been able to secure this desperately needed capital and/or would not have been able to negotiate the favorable terms under which it was acquired.
 - 2. At the Time of the April Equity Offering, the Company's Stock was Trading at Artificially Inflated Levels Due to Defendants False and Materially Misleading Public Statements
- 135. As previously alluded to, the Company made the various false and materially misleading statements concerning the safety and clinical trial progress of PMX-60056 in order to keep its stock price artificially inflated. This allowed PolyMedix to charge investors more for the twenty-five million units sold during the April Equity Offering than it would have been able to charge had the risks associated with the development of PMX-60056 been known by the market. As it stands, the Company secured over \$18.4 million dollars in connection with the April Equity Offering.

- 136. Given that PolyMedix stock closed at \$0.64 per share on April 8, 2011 (the last business day prior to the close of the April Equity Offering), the \$0.80 paid per unit in the April Equity Offering implies that investors were willing to pay a 25% premium to the Company's trading price per unit. Had this premium been applied to the \$0.36 per share closing price of the Company's stock on May 11, 2012 (the day after Defendants revealed the truth about PMX-60056), the implied price per unit offered in the April Equity Offering would have been just \$0.45, with net proceeds equaling just \$9.7 million.
- 137. Accordingly, by artificially inflating the per share price of the Company through the misinformation it fed the public, Defendants were able to secure an additional \$8.7 million of funding which was essential to the continued development of its remaining clinical trial program PMX-30063. This capital came at the expense of investors, who were deceived into paying a 25% premium for one share of PolyMedix stock and a warrant which, unbeknownst to them, is likely to be out-of-the money for the entirety of the time during which it is exercisable. ¹³
- 138. Notably, *none* of the Defendants acquired any units in connection with the April Equity Offering, further demonstrating that they knew of the safety issues concerning PMX-60056 and were unwilling to invest their own money in a Company with no means of generating revenue and only one potentially viable product in its pipeline. Had the investing public had access to this same information they would have made the same decision and stayed away from PolyMedix entirely.

¹³ Since PolyMedix announcement that it was discontinuing the development of PMX-60056, its stock has traded nowhere near the \$1.60 per share that would merit exercising the warrant. In fact, the stock has failed to close at even \$0.40 per share, meaning the stock price would have to increase by well over 300% for the warrant to have any value. This alone is unlikely. However, when one considers that the Company's stock closed at just \$0.13 per share on January 24, 2013, the chances of the warrants ever being exercised is astronomical.

C. The Company Misled Investors About the Progress of the Phase II Study Until the MidCap Credit Facility Was Fully Funded

- 139. The cash from the April Equity Offering was not sufficient to keep the Company operating for long. Accordingly, PolyMedix devised a plan to refinance its debt obligations under the existing Hercules Credit Facility on more favorable terms while simultaneously obtaining the additional operating capital it so desperately needed. Ultimately, this plan resulted in the Company entering into the \$12 million MidCap Credit Facility on April 5, 2012, pursuant to which it received an immediate advance of \$8 million.
- 140. The Company was so desperate to obtain this funding that it was willing to mislead MidCap as well in order to secure it. In fact, during negotiations regarding the MidCap Credit Facility, PolyMedix specifically represented in the 2012 8-K that "there [had] been no adverse clinical test results of which [it had] been made, or reasonably should be, aware" with respect to either PMX-60056 or PMX-30063. This was clearly not the case given that the Company's initial Phase I studies had revealed significant hypotension concerns associated with the use of PMX-60056 and that the Company was certainly aware by this time that the then ongoing Phase II Study, which was discontinued only weeks later, had shown a significant risk of hypotension.
- 141. As a result of this blatant misrepresentation to MidCap, the Company was able to secure the following terms in connection with the MidCap Credit Facility: (i) a fixed interest rate of 11.95%; (ii) interest-only payments until January 1, 2013; (iii) and a payment due date of July 1, 2015. These terms are noticeably more favorable than those contained in the Hercules Credit Facility. Indeed, in its April 10, 2012 press release announcing the debt restructuring with MidCap, the Company touts these benefits, stating: "We are very pleased with this new facility, which refinances at a lower cost of capital, improves our cash flow, and strengthens our balance sheet. All of these provide us with greater flexibility in advancing the development of our programs." Assuming an interest rate on the Hercules Credit Facility of just 12.35% (the lowest possible rate given the agreed upon variable interest rate range of 12.35-14%), these beneficial terms decreased the monthly debt payments made by the Company by approximately \$280,000

from April 2012 to June 2012; approximately \$293,000 from June 2012 to January 2013; and approximately \$100,000 for every month thereafter.

- 142. The MidCap Credit Facility also provides the Company with a number of other perks which, in light of the events which transpired shortly after the agreement was executed, combine to create a strong inference that Defendants: (i) were knowingly making false and materially misleading statements concerning the safety and clinical trial progress of PMX-60056 during the Class Period; and (ii) were misleading the market into believing that the ongoing Phase II Study concerning PMX-60056 was proceeding as planned until such time as the funds from the MidCap Credit Facility were distributed and the Hercules Credit Facility had been closed.
- 143. First, Defendants carefully negotiated the default provisions of the MidCap Credit Facility so as to ensure that they could discontinue the development of PMX-60056 without defaulting on the loan. Indeed, Section 8.14 of the MidCap Credit Facility specifically states that an "event of default" occurs only if the Company voluntarily "ceases clinical development for both PMX-60056 and PMX-30063." Moreover, Section 8.14 goes on to state that "the failure of any clinical or non clinical trial to demonstrate the desired safety or efficacy [of PMX-60056] ... shall not constitute an Event of Default." Notably, the Hercules Credit Facility contained no such provision.
- 144. By ensuring that the MidCap Credit Facility allowed it to discontinue development of PMX-60056 without the threat of defaulting, the Company avoided the severe effects an event of default would have on its business. The 2012 10-K discusses these risks when it states:

We have pledged substantially all of our assets, other than our intellectual property, as collateral to secure certain credit facilities and have provided the lenders with remedies in the event of a default, including the ability to collect and liquidate the collateral.

If we do not make required payments to our secured creditors or otherwise experience an event of default, our secured creditors may exercise all remedies

- available [] to them under the applicable credit agreements and applicable law, including acceleration of our obligations to them and the collection and liquidation of the collateral. While we have not pledged our intellectual property as collateral, we have pledged the rights to any payments and proceeds from the sale, licensing or disposition of all or any part our intellectual property.
- 145. Second, Defendants strategically timed their decision to enter into the MidCap Credit Facility so as to coincide with the 1% drop in the pre-payment penalty agreed to in connection with the Hercules Credit Facility. As discussed in section IV.H.2 above, the Hercules Credit Facility required the Company to pay a 2% penalty on any principal being pre-paid prior to March 31, 2012. However, this pre-payment penalty dropped to just 1% of any pre-paid principal after March 31, 2012. Thus, by waiting until April to pay off the \$5.6 million balance on the Hercules Credit Facility, PolyMedix saved upwards of \$55,000.
- 146. By closing the Hercules Credit Facility before announcing the discontinuation of PMX-60056, PolyMedix was also able to lock in the exercise price on the warrant issued to Hercules in connection with the Hercules Credit Facility. The warrant entitles Hercules to acquire 627,586 shares of PolyMedix Common stock at an exercise price equal to the lesser of: (i) \$1.16; or (ii) the twenty-day volume-weighted average price of PolyMedix stock prior to the closing of the Hercules Credit Facility.
- 147. Because PolyMedix closed the Hercules Credit Facility on April 5, 2012 when the Company's stock was trading near the Class Period high the prior twenty-day volume-weighted average closing price of PolyMedix stock was \$1.22 per share. Had the Company announced it was discontinuing its development of PMX-60056 prior to paying off the Hercules Credit Facility the exercise price of the warrant would have been much lower. In fact, the volume-weighted average price of PolyMedix stock for the twenty days following the May 10, 2012 disclosure concerning PMX-60056 was a mere \$0.35 per share.
- 148. Accordingly, by closing the Hercules Credit Facility when they did, Defendants guaranteed that the Hercules' warrant was exercisable at the highest possible price. Indeed, should Hercules now exercise its right to acquire all 627,586 PolyMedix shares available to it

under the warrant, the Company will receive approximately \$730,000 – 230% more than the \$220,000 would have received had it waited to close the Hercules Credit Facility.

- 149. Given that the Company's stock is currently trading at around \$0.13 per share, it will be some time before Hercules even considers exercising its rights under the warrant. Thus, Defendants' decision to release the news concerning PMX-60056 after it closed the Hercules Credit Facility had the added benefit of preventing Defendants' own holdings in the Company from being diluted.
- 150. Finally, while the MidCap Credit Facility also called for the issuance of a warrant, this warrant was distinct from the one issued to Hercules in that it had a fixed exercise price of \$1.24 for each of the 161,290 shares to which it applies. At the time the MidCap Credit Facility was agreed to, the Company's stock was trading at around \$1.20 per share, making the exercise price on the warrant appear reasonable. However, after the PMX-60056 announcement just one month later, that was not the case at all and, like Hercules, MidCap was left with a warrant that is unlikely to ever have any value.
- 151. The timing of the Defendants' decision to enter into the MidCap Credit Facility and the issuance of the subsequent press release announcing the discontinuation of PMX-60056 is highly suspect. For Defendants to pull the plug on the development of PMX-60056 just over a month after refinancing its existing debt obligations on much more favorable terms and obtaining additional, much needed capital, is far from a coincidence despite Defendants' assertions to the contrary.
- 152. In addition, the fact that after PolyMedix announced the end of its PMX-60065 program, MidCap forced it to renegotiate the terms of the loan agreements including requiring PolyMedix to pay back a portion of the loan, strangely suggests that MidCap believed it had been misled about the safety and liability of the PMX-60056 program.
- 153. Taken as a whole, the aforementioned facts demonstrate or, at a minimum, create a strong inference that Defendants knowingly withheld material information concerning the safety and clinical trial progress of PMX-60056 from investors until such time as they were able

to refinance the Company's debt on the best possible terms. As a result, shareholders were irreparably injured when the truth about PMX-60056 was ultimately revealed in May of 2012 – causing the Company's stock price to crumble.

IX. FRAUD-ON-THE-MARKET AND THE PRESUMPTION OF RELIANCE

- 154. At all relevant times, the market for PolyMedix securities was an efficient market for the following reasons, among others:
- (a) There has been a substantial volume in PolyMedix securities during the Class Period;
 - (b) PolyMedix filed periodic public reports with the SEC; and
- (c) PolyMedix regularly communicated with public investors via established market communication mechanisms, including regular disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services.
- 155. As a result of the foregoing, the market for PolyMedix securities promptly digested current information regarding PolyMedix from all publicly available sources and reflected such information in the prices of the securities.
- 156. Under these circumstances, all purchasers of PolyMedix securities during the Class Period suffered similar injury through their purchase of PolyMedix securities at artificially inflated prices and are presumed to have relied on all the publicly available information concerning PolyMedix in making such purchases.

X. NO STATUTORY SAFE HARBOR

157. The statutory safe harbor for certain forward-looking statements provided under the Private Securities Litigation Reform Act of 1995 does not apply to any of the allegedly false statements plead in this Amended Complaint. The statements alleged herein to be false and materially misleading all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful

cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

158. To the extent that the statutory safe harbor is determined to apply to any forward-looking statements plead herein, Defendants are liable for those false forward-looking statements because, at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was false or materially misleading, and/or the forward-looking statement was authorized or approved by an executive officer of PolyMedix who knew that the statement was false when made.

XI. CONTROL PERSON LIABILITY

- 159. The Individual Defendants are liable as direct participants with respect to the wrongs complained of herein. Given their status as senior executive officers and/or directors of the Company, the Individual Defendants were "controlling persons" within the meaning of Section 20(a) of the Exchange Act, and had the power and influence to cause the PolyMedix to engage in the unlawful conduct complained of herein. Specifically, the Individual Defendants were able to, and did, directly or indirectly control the conduct of PolyMedix's business during the Class Period.
- 160. The Individual Defendant possessed the power and authority to control the contents of PolyMedix's annual and quarterly reports, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors (i.e. the market) including those reports, press releases, and presentations containing the false and materially misleading statements and omissions of material fact alleged herein. Given their respective management and/or board positions with the Company, the Individual Defendants also had the ability and opportunity to review copies of PolyMedix's allegedly misleading SEC filings, reports, and press releases prior to, or shortly after, their issuance and to cause such misleading statements to be corrected.
- 161. Further, the Individual Defendants had access to a plethora of material, non-public information concerning PolyMedix and its operations. Given this insider information, the

Individual Defendant knew and/or recklessly disregarded the fact that certain adverse facts concerning the safety and clinical trial progress of PMX-60056 had not been adequately disclosed and were being concealed from the public, and that certain positive representations concerning PMX-60056 were false and materially misleading at the time they were made public.

XII. CLASS ACTION ALLEGATIONS

- 162. Lead Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of itself and the Proposed Class. Excluded from the Proposed Class are Defendants, the Company's officers and directors during the Class Period, members of Defendants' and the Company's officers and directors' immediate families, and any firm, trust, partnership, corporation, or other entity in which a defendant has/had a controlling interest, or which is otherwise affiliated with any defendant, and the legal representatives, heirs, successors-in-interest, or assigns of such excluded persons.
- 163. The members of the Proposed Class are so numerous that joinder of all members is impracticable. Absent appropriate discovery, Lead Plaintiff cannot ascertain the precise number of Proposed Class members, however, as of March 7, 2011 (the beginning of the Class Period), PolyMedix had 80,999,610 shares of common stock outstanding with over 106 million shares outstanding at the end of the Class Period on May 10, 2012. At all times, these outstanding shares were owned by hundreds, if not thousands, of persons many of whom are believed to be members of the Proposed Class. ¹⁴ The disposition of their claims in a class action will provide substantial benefits to the parties and the Court.
- 164. Questions of law and fact common to the Proposed Class as a whole predominate over any questions that affect individual Proposed Class members. These common questions of law and fact include:
 - (a) whether Defendants' conduct as alleged herein violated the Exchange Act;

¹⁴ As of the beginning of the Class Period, PolyMedix had approximately 700 holders of record of its shares of common stock.

- (b) whether Defendants publicly disseminated documents, or otherwise made public statements, during the Class Period which omitted and/or misrepresented material facts;
- (c) whether Defendants' public statements during the Class Period omitted material facts necessary to make other public statements, in light of the circumstances under which they were made, not misleading;
- (d) whether Defendants acted with scienter in making the false and materially misleading statements and omissions alleged herein;
- (e) whether the price of PolyMedix securities was artificially inflated during the Class Period as a result of Defendants' misconduct;
- (f) whether the Individual Defendants were controlling persons of PolyMedix during the Class Period; and
- (g) whether members of the Proposed Class have sustained damages as a result of Defendants' violations of the Exchange Act, and the extent (and appropriate measure) of such damages.
- 165. Lead Plaintiff's claims are typical of those of the other Proposed Class members because Lead Plaintiff and the Proposed Class sustained damages arising out of Defendants' wrongful conduct as alleged herein.
- 166. Lead Plaintiff will fairly and adequately protect the interests of the Proposed Class and has no interests that are contrary to, or in conflict with, those of the other Proposed Class members. Lead Plaintiff has also retained competent counsel experienced in class action securities litigation under the federal securities laws to vigorously prosecute this action on behalf of the Proposed Class.
- 167. A class action is superior to other available methods for the fair and efficient adjudication of this controversy as, among other things, the damages suffered by the individual members of the Proposed Class may be relatively small, making the expense and burden of bringing separate actions to seek redress for the wrongs alleged herein impossible. Additionally, the prosecution of separate actions by the individual members of the Proposed Class would

create a risk of inconsistent and varying adjudications, which could establish incompatible standards of conduct for Defendants.

168. There will be no difficulty in the management of this action as a class action.

COUNT I

Against Defendants for Violation of Section 10(b) of the Exchange Act and SEC Rule 10b-5

- 169. Lead Plaintiff incorporates by reference and realleges each and every allegation above as if fully set forth herein.
- 170. During the Class Period, Defendants disseminated or approved the false statements specified herein. Defendants knew, or recklessly and deliberately disregarded the fact that, such statements were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.
- 171. Defendants violated section 10(b) of the Exchange Act and SEC Rule 10b-5 in that they:
 - (a) employed devices, schemes, and artifices to defraud; and
- (b) made untrue statements of material fact or omitted material facts necessary to make the statements made not misleading; or engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Lead Plaintiff and others similarly situated in connection with their purchases of PolyMedix securities during the Class Period.
- 172. Plaintiff and the Proposed Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for PolyMedix securities. Plaintiff and the Proposed Class would not have purchased PolyMedix securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' false and materially misleading statements.

COUNT II

Against the Individual Defendants for Violation of Section 20(a) of the Exchange Act

- 173. Lead Plaintiff incorporates by reference and realleges each and every allegation above as if fully set forth herein.
- 174. Defendants Landekic and Smith acted as controlling persons of PolyMedix within the meaning of section 20(a) of the Exchange Act. By reason of their positions of control and authority within the Company, Landekic and Smith had the power and authority, directly or indirectly, to cause PolyMedix to engage in the wrongful conduct complained of herein. Landekic and Smith controlled PolyMedix and all of its employees. By reason of such conduct, Landekic and Smith are liable pursuant to section 20(a) of the Exchange Act.
- 175. As a direct and proximate result of defendants Landekic and Smith's wrongful conduct, Lead Plaintiff and members of the Proposed Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff prays for relief and judgment as follows:

- A. Declaring this action to be a proper class action pursuant to Rule 23 of the Federal Rules of Civil Procedure and certifying Plaintiff as a representative of the Proposed Class;
- B. Awarding Lead Plaintiff and the other members of the Proposed Class damages, including interest;
 - C. Awarding Lead Plaintiff reasonable costs, expert fees, and attorneys' fees; and
- D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Lead Plaintiff hereby demands a trial by jury pursuant to Rule 38(b) of the Federal Rules of Civil Procedure.

Date: January 25, 2013 RYAN & MANISKAS

/s/ Richard A. Maniskas RICHARD A. MANISKAS

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Additional Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on January 25, 2013, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the email addresses denoted on the Court's electronic mail notice list.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed January 25, 2013.

/s/ Richard A. Maniskas RICHARD A. MANISKAS (PA #85942)